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CIT-PART
Deliverable 3

Overview on XTP policies and related TA/PTA procedures

Nik Brown, Siân Beynon-Jones (Eds.)

With contributions by Agnes Allansdottir, Meaghan Brierley, Edna F. Einsiedel, Erich Griessler, Kristofer Hansson, Mavis Jones, Daniel Lehner, Susanne Lundin, Anna Pichelstorfer & Anna Szyma

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2010

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1 Introduction and Summary

The aims of the workpackage: The objective of WP3 is to provide an overview of policy formation and deliberation across a number of regions and across a relatively broad timeframe (late 1980s to the present). As a mapping exercise it is intended to provide an initial comparative framework for further elaboration in more detailed country and regional case studies. WP3 offers a 'helicopter view' of global xenotransplantation (XTP) regulation and landmark policy events. It provides a history of the development and timeline of policy-making combined with an initial scoping of the place and purpose of consultative and deliberative processes. In so doing, the WP provides a means of initial orientation for future comparative work and more in depth case studies. The WP is in no sense intended to be comprehensive but instead provides an initial means of developing a more focussed comparative method and body of questions to be taken up in the project's future workpackages.

Scope: In light of the goals and scope of the CIT-PART project the sample focuses primarily on the question of citizen participation in the European context. However, in order to contextualise events in Europe in relation to broader global developments in XTP science and regulation, this overview also examines the role of supranational bodies (the OECD, the Council of Europe, the WHO) in shaping the policy-making agenda, as well as considering XTP in three non-European comparator countries: Canada, Japan and the US. The US provides a particularly important source of data because, historically, it has been a world leader in clinical XTP activity. Canada also represents a critical site for detailed comparative analysis because it instigated an unusually high profile public consultation on XTP in the early 2000s. Finally, Japan is an interesting case for comparison because it is widely perceived as a country with an unusually low level of human organ donation.

The XTP paradox: In comparison to other areas of biotechnological innovation, XTP could be said to represent a particularly compelling case for the importance of public consultation. This is because the benefits that it promises to individual patients are potentially in conflict with the population-wide risks generated by XTP, specifically, the risk of transpecies infection. Through this unique combination of private benefit vs. public risk, XTP can be seen to exemplify deeper political tensions between neoliberalism (individualised free choice, health care consumption, etc) on the one hand and risk-averse public health-oriented governance on the other.

XTP and national economic strategies: For some member states, XTP together with other areas of innovation in the biosciences promised (and are still taken to promise) significant economic and medico-industrial potential. Again, this varies significantly from country to country depending on contrasting histories of their respective positions within an internationally competitive bioscience sector. Some of the first efforts to instigate expert

debate on XTP in the mid 1990s were undertaken by the OECD (1996) with an emphasis on the economic and commercial dimensions together with potential healthcare costs associated with the approach. A number of countries reviewed here have intense commercial involvement in the health and life sciences as the basis for future economic and industrial advantage. Indeed, a small number of countries have been at the forefront of primary research and industrial sponsorship of XTP specifically. From the 1960s onwards the US has continued to invest in and lead research, as well as clinical activity, in this field. During the 1990s, the UK was also home to several major XTP institutions including the Cambridge based company Imutran, the Edinburgh based PPL Therapeutics and the quasi-public Roslin Institute. Huntingdon Life Science, where much of the UK's preclinical XTP work took place throughout this period, has been vigorously championed by the government as central to the future of the UK's commercial investment in bioscience. Likewise, the position of big pharma within the Swiss and German contexts is not insignificant in the political handling of the XTP case, particularly given the long-term financial investment of Basel's Novartis, Imutran's parent company. It is important to reflect upon whether and to what extent this vision of an emerging bioeconomy has manifested itself in political efforts to win over sceptical publics through a more neoliberal discourse of open engagement, debate and transparency.

XTP Research: Whilst commercial investment in XTP was restricted to relatively few European countries, there has been some significant public sector research in countries like Sweden, Poland, Denmark, Germany and Belgium. Indeed, both Sweden and Poland remain the only European countries to have undertaken human clinical xenograft studies, in 1989 and 1990 (to 1993) respectively. Again, it may be useful to draw attention to the place of high profile research programmes in triggering debate and to consider how this translates into more focussed attempts at consultation.

The European GM debate: The decade in which interest in XTP peaked (the mid to late 1990s) was also a period in which many countries, particularly within the European context, saw ferocious controversy centred on GM plants and animals. Whilst most governments were, to varying extents, committed to promoting new transgenic-based industries, this was strikingly at odds with public sentiment about the future of both food and medicine. For instance, the discussion of the UK and Norway below can be seen to illustrate this acute tension between political commitment to promoting transgenic-based industries and wider public scepticism. It is crucial not to conflate the public standing of green and red bioscience given that much of the evidence (for example, data provided by Eurobarometer Special surveys, which are analysed in the annex to this WP) suggests strong political distinctions between each. Nevertheless they were and continue to have a central place in a public discourse centred on the risks of bio-industrial innovation.

XTP regulation: It has also been important to recognise and map out the diverging regulatory and policy routes taken even within and across Europe. This ranges from an

almost complete absence of any kind of legislative or stated policy agenda (Austria, Republic of Ireland, Greece, many of the accession states) to highly formalised legal structures for assessment, accreditation and approval. There is also wide variation in the degree to which European countries can be considered to be either permissive or restrictive. Poland and Switzerland, having been directly involved in the clinical application of XTP, can both be characterised as having constructed relatively permissive legal frameworks. This may also now be said to apply to the UK following the cessation of its regulatory authority (UKXIRA) and the delegation of responsibility to local ethics review. Key variations in XTP regulation have also emerged outwith Europe, for example between the US and Canada, which have adopted permissive and restrictive XTP policies respectively.

Supranational bodies: XTP, as with other highly controversial areas of life science innovation, has had a high profile on the agendas of supranational bodies such as the European Council, the Commission, the Organisation for Economic Cooperation and Development (OECD) and the World Health Organisation (WHO). Heavily influenced by an emerging discourse centred on the precautionary principle, the Council of Europe took action in 1997 to recommend a moratorium on XTP although this was not adopted by the Parliament until 1999 and remained non-binding by most member states. The European Commission, through a range of instruments, has sought to harmonise regulatory oversight though this has been only partially successful and has preserved the scope for far-reaching variation throughout the Eurozone. It has also played a significant role in generating data on changing values and views through a series of Eurobarometer Special surveys. The OECD has provided a means of developing intelligence on regulatory developments in different member states with its stated aim of promoting economic and industrial development. The WHO has been highly significant in establishing binding measures for biosurveillance and monitoring of recipients, as well as establishing global standards for the import and export of transgenic animals used in preclinical and indeed clinical trial research.

XTP and public debate: The countries reviewed here also reflect widely divergent engagements with XTP as a topic for public, political and popular debate. For instance, given the major transitions faced by accession states throughout this period, it is unsurprising that developments in the health and life sciences have had marginal attention either in the popular press, or indeed in expert regulatory circles, let alone organised public consultation. Amongst other countries in Europe, some have seen very significant levels of media attention (UK, Nordic countries, etc) whilst others have seen very little if any (Austria, Belgium, Greece). Italy, for instance, with considerable public research investment in preclinical XTP has seen little wider debate.

The meaning of debate: We should however make clear that this analysis does not seek to make assumptions about what the term ‘debate’ means and that the focus on XTP as a topic for discussion is unequally reflected in different contexts and fora. In most of the country contexts discussed in greater depth below, the ‘xenotransplantation debate’ has been almost

exclusively confined to expert ministerial and regulatory circles. In fact, the brief review provided here shows that rarely, if ever, is this policy concern actually translated into investment in wider public stakeholder engagement, even if this is stated as a priority by advisory or regulatory agencies. Almost all regulatory and advisory agencies have recommended broadening the range of consultation and involving wider public stakeholders. But in fact very few such recommendations have resulted in firm consultative action. Notable exceptions to this trend are provided by the cases of Canada, Switzerland and the Netherlands, and these examples are discussed in further detail below. On the whole, however, in spite of the increased move over the last decade or so towards collaborative multi-stakeholder policy-making, experiments in deliberative engagement on this topic are rare and tend to be initiated by academic communities and not directly by policy communities. Examples where this has been particularly the case include the UK and Germany.

Theistic traditions: In some country contexts (for example, Austria and Italy), faith-based systems of belief have had a defining role with respect to debates on the life sciences generally and occasionally with respect to XTP specifically. However, there are clear distinctions here between, on the one hand, life science regulation on reproduction and, on the other, the regulation of animal and plant biotechnology. Whilst the former tends to be heavily proscribed, animal transgenics occupies something of a more ambivalent place within a traditional Judaeo-Christian cosmology (and indeed its secular versions) in which animals and the natural are conceptualised theistically as both resource and creation. A Vatican Committee report in 2001 illustrates these tensions by strongly endorsing XTP as a significant and important alternative to human embryonic stem cells (hESC).

Animal advocacy: Very few of the countries or regions under review here have a notably strong culture of animal advocacy, with the exception of the UK where there are clearer indicators pointing to strong ambivalence and scepticism about the use of animals in biotechnological research. However, even in this case the issue is strongly polarised between a discourse of animal welfare on the one hand, and that of a perceived militancy amongst those who identify themselves with an animal rights agenda.

The structure of this report: The discussion introduced here and in the following pages summarises a series of regional and country reports compiled in the preparation of this WP. Each of these reports have been abridged and included as an annex, and can be found in the final section of this document. In what follows we first outline the methods used in compiling the regional and country reports, the countries included and the common framework used by authors of the reports. We then document a timeline for key events in the evolution of policy and debate on XTP with reference to broader factors and developments in the science. This is followed by a discussion which characterises the emergence and function of public consultation on XTP and its implications for policy making. We have chosen to characterise the relationship between policy and consultation as either relatively

permeable (open and porous) or much more impermeable with clear evidence of firm boundaries operating between consultative events and actual policy formation.

2 Summary of Methods

This review summarises a series of country case studies each drawing on an analysis of secondary gray literature stretching back over the course of the last two decades to the end of the 1980s and defined as follows:

- Public engagement, opinion surveys and consultations where XTP has been either the central or peripheral objective within a consultative activity;
- Social and political science commentary seeking to characterise the dynamics of engagement and citizenship in science policy;
- Reviews and commentary on the changing institutional characteristics of regulation pertaining to XTP including non-governmental advisory reports;
- Other relevant policy publications, meeting minutes, memorandums;
- News and commentary.

Each country case review sought to produce a timeline of the relationship between key events in policy-making and the place given to broadly defined examples of public consultation.

The review covers developments in the following country and institutional contexts:

- Supranational bodies including – OECD, WHO, the Council of Europe as well as the EU.
- European country contexts including the Austria, France, Germany, Italy, The Netherlands, Sweden, UK, Spain, Norway, Denmark, Belgium, Greece, Republic of Ireland, Poland, Portugal, Switzerland, Bulgaria, Cyprus, Czech Republic, Hungary, Latvia, Malta, and Slovak Republic.
- Non-European country comparators: Canada, Japan and the US.

The WP includes a basic bibliometric of science and news features and articles related to XTP during the period 1988-2008.

3 A XTP timeline: policy, science and social change

Introduction: Pages 15 to 18 below figuratively document a timeline for the development of both the science and policy specific to XTP but also alongside wider events and episodes that have had a major impact on the putative move towards a consultative science policy-making. The timeline discussed in greater depth below demonstrates a general pattern in which basic research and clinical activity in the late 1980s and early 1990s triggers expert-based policy-making and regulatory activity that peaks in the late 1990s. This is followed in the early and mid 2000s by a number of public consultative events but which, on the whole, were marginal to policy-making. The very fact that regulatory and policy activity peaked in the late 1990s, and that this occurred some considerable time before wider stakeholder engagement in the early 2000s, illustrates a striking temporal disjuncture between deliberative consultation and policy.

The Science: Figures 1, 2 and 3 present quantitative measures of the development of the science and debate associated with the XTP field generated through a basic bibliometric of scientific articles and news features published between 1988 and 2008. Figure 1 shows that whilst the fortunes of XTP have changed very significantly during this period, the field itself remains a constant and ongoing focus of research investigation. Bibliometric citations for ‘xenotransplant’ were relatively low throughout the late 1980s and early 1990s but rose very sharply from 1994, peaking in 2000 and falling sharply in 2001. The sharp fall in scientific articles corresponds to an equally sharp rise in articles addressing porcine endogenous retrovirus (PERV), following the original report by Weiss et al on porcine-to-human trans-infectivity in culture in 1997. Nevertheless, throughout the mid 2000s to the present a surprising amount of scientific publishing has focused on XTP. Present citation hits today are roughly equal to those of the peak in 2000. Figure 2 shows a more steady and constant pattern in the increase of citations for the search term ‘xenograft’ – though much of this activity is only distantly related to XTP it nevertheless demonstrates continued and sustained research activity in relevant areas and models. Figure 2 also presents data on citations for ‘zoonoses’ which rose from 84 to 751 during the timeframe 1988 to 2008.

Media attention: Figure 3 shows a quite different patterning in the publication of news and commentary throughout the same period. The peak in features around 2000 is entirely consistent with the same peak in science articles. However, rather than recovering, the attention given to XTP in the media has continued to decline throughout that period. That decline has been consistent with a perceived and arguably real loss of confidence in the potential of the XTP field to deliver on the kinds of expectations associated with it in the mid to late 1990s.

The Timeline: Pages 16 to 18 diagrammatically present key events in science and policy from the 1980s through to the present. For the 1990s and 2000s, we have chosen to present

key scientific and clinical events in XTP on the left hand side of each page, together with some broader developments and events such as the BSE/CJD crisis, the GM crisis, etc. The right side of each page presents developments in policy-making and consultation.

The 1980s: This is an important and formative period for the field, particularly in respect of the subsequent shaping of regulatory behaviour and policy. In terms of policy-making it commences with the publication of the influential EC *Biosociety Report* (1979) which explicitly identifies biotechnology as the key focus for European industrial competitiveness in the two decades to come. Any number of commentators, at the time and since, have commented on the emerging disjuncture between this as an economic agenda and a nascent awareness of a public cultural politics of ambivalence.

In terms of clinical developments, the highly controversial 'baby Fae' episode (1984) in which a newborn infant was unsuccessfully xenografted with a baboon heart began to put the question of XTP into wider circulation. The incident received widespread media coverage in the US and to a more limited extent in Europe providing a recognisable and tangible association for an otherwise abstract and esoteric area of clinical development. In 1989 a clinical team in Warsaw undertook an equally unsuccessful porcine to human xeno-cardiagraft although there is little evidence that this became the focus of any kind of concerted debate beyond expert regulatory circles.

The 1980s is also a crucial time for the field in other more tangential respects. The decade opens with the announcement in 1981 by the Centre for Disease Control in Atlanta of a rare though fatal human immune deficiency virus (HIV1). By the mid 1980s, an emerging consensus surrounding the transpecies origins of HIV is confirmed in 1985 by a French research team firmly establishing a link between human and simian immune deficiency virus (SIV). The implications of this for xenotransplantation slowly become more evident with intensifying concerns surrounding potential transpecies-infectivity. The identification of BSE in cattle in 1986 adds further weight to both public and expert-regulatory concerns about disease aetiology and the boundaries between species. Both these events would later become decisive in setting the terms of expert-regulatory concerns towards the end of the 1990s to the present. As one influential 2001 report would later put it:

'The AIDS (acquired immunodeficiency syndrome) and BSE (Bovine Spongiform Encephalopathy) public health crises have emphasised the need for caution. The European Commission should be aware of this public sensitivity and measures taken to give the public confidence that the risks of xenotransplantation will be thoroughly examined.' *Opinion on the State of the Art concerning Xenotransplantation*. *Adopted by The Scientific Committee on Medicinal Products and Medical Devices on 1st. October 2001*

Despite this the 1980s see very little direct policy-making in Europe on XTP. Nor is there any significant or direct effort to generate public debate.

The 1990s: This is by far the decade in which XTP as a relatively near-term clinical reality enters the horizon of public and regulatory awareness. It is the decade in which the twin-crisis surrounding GM and BSE comes to a head and a period that closes with fundamental questions about a perceived 'crisis of trust' in science and the need to reshape the civic-science interface through a more deliberative and potentially consensually democratic ethos. Nevertheless, it is also a decade which sees very little if any practical manifestations of deliberative public engagement, certainly on the question of XTP, and in which much of the regulatory and advisory activity is constructed through traditionally elite policy networks.

The early 1990s follow directly from the close of the previous decade with the US continuing to dominate global clinical XTP research, and with European examples of human clinical XTP shifting from Poland (1989) to Sweden (1990-1993). Early modest attempts by Swedish clinicians to implant porcine islet cells into diabetic patients are followed in 1995 by a kidney xenoperfusion trial. Both of these events become the focus of some considerable public discussion in Sweden but this by no means manifests itself in any early or comprehensive regulatory activity. In 1993, as Starlz undertakes two ill-fated baboon-to-human liver transplants in the US, Imutran in the UK announces the birth of its first transgenic pig, triggering some significant media attention worldwide. By 1996 Imutran has been acquired as a subsidiary of the Swiss pharma giant Sandoz consolidating Europe's place in the development of the technology. By 1999 Imutran has publicly announced its immanent intention to seek clinical trial approval from the regulator, UKXIRA. In retrospect, however, this was possibly a promotional move to detract from poor preclinical trial results and an attempt to sustain financial and regulatory support at a critical moment for the future of the company. Meanwhile, a network of Danish scientists also announces in 1999 their intention to produce transgenic knock-out pigs for XTP.

The mid-1990s is a protracted phase of acute crisis both for the nascent field of XTP and for European science and industry itself. 1995 sees the first documented fatality attributable to CJD, the human form of the bovine pathogen. That is followed by a ban on exports of beef from the UK to the rest of Europe in the following year. In 1997, Robin Weiss publishes the results of a study confirming the cross-infectivity of PERV into human tissues in culture. Similar results are obtained by FDA researchers in the US, and a German study confirms the presence of PERV in key transplantable porcine tissues (heart, kidney, liver, etc). Zoonoses is by now very firmly established as a recognized and potentially 'show stopping' factor in the international regulation of the field (see fig 2).

In terms of policy-making, significant activity is slow to commence with very little direct engagement with XTP before 1995 when a draft report by the French National Transplant Agency is published. However, from this period onwards there is a striking and intense focus on XTP by many national and international agencies. 1996 sees the influential publication of the UK Nuffield Report and the launch of the first expert OECD workshop with a focus on XTP's economic aspects. At the same time the Dutch Health Council is commissioned to

undertake a wide-ranging report and the question is raised for debate in the Swedish Parliament (following a Swedish xenoperfusion trial taking place the previous year).

Somewhat at odds with the more precautionary position adopted elsewhere during the mid-1990s, Poland institutionalizes a law permitting XTP in 1996. Similarly, although US policy appears to acknowledge the risks of XTP (as evidenced, for example, by the Public Health Service agencies' draft *Guidelines on Infectious Disease Issues in Xenotransplantation* in 1996), clinical trials are allowed to proceed.

By 1997 there is considerable policy momentum dedicated to XTP with the publication of the UK Department of Health's 'Kennedy Report' recommending the creation of a statutory regulatory authority (UKXIRA was established that year as an 'advisory' rather than a 'statutory' body), the German Green party pushes for government action in Parliament, and the Council of Europe proposes and approves a motion recommending an EU-wide moratorium. A voluntary moratorium is adopted in Sweden ceasing clinical trial development and a national committee is established.

The first wave of policy-making occurs in 1998 with a number of countries supporting the potential licensing of clinical trials in principle. The Dutch Health Council backs the approach as a significant contribution to improving transplantation rates and UKXIRA publishes its guidelines on applications to conduct clinical trials. In the US, the FDA responds to the discovery of PERV transpecies-infectivity by briefly halting clinical trials in order to impose new safety criteria (trials resume five months later), and the OECD holds its second major expert conference jointly convened with the New York Academy of Science. The following year, the US Department of Health and Human Services establishes the Secretary's Advisory Committee on Xenotransplantation (SACX) in order to inform the governance of XTP. 1999 also sees a raft of reports and position statements being published in Denmark, France and Norway, with the latter proposing a temporary ban. Significantly, this year is also the first time that major discussion of XTP policy occurs in Japan where, during the 5th Meeting of the International Xenotransplantation Association, advocates of XTP frame the technology as a solution to Japanese antipathy towards human organ donation.

Almost all of the policy-making during this period highlights the importance of undertaking wider public debate about a technology which is at this time (amongst policy communities at least) seen as immanently realizable. And yet, with very few exceptions (discussed below), expressions of a desire to widen discussion beyond expert elites come to nothing.

Most of the regulatory and advisory bodies established during this period engage in a passive form of consultation inviting written responses to draft reports and documents within a fixed timeframe. Final reports tend to draw selectively on these representations which, on the whole, are contributed by institutions and advocacy organisations with a recognized

interest in the technology. Rarely, if ever, is it the case that active consultation work is undertaken amongst 'non-invested' public constituencies.

There is however a number of consultative activities throughout the 1990s where XTP features as either one amongst a number of technologies, or as a primary focus for deliberative debate in its own right. Amongst the earliest here is the 1996 Biocult comparative survey of 11-18 year olds in Finland, Germany, Spain and the UK funded by the EU's Biotech Programme. The methodology on which this was based, a combination of quantitative and narrative approaches, is later expanded to include New Zealand and Japan.

A number of further surveys are conducted in the late 1990s. There are quantitative attitude surveys undertaken in 1998 in France and Australia, an academically led survey and technology assessment in Germany and a public consultative conference in Sweden. This is followed by a telephone survey undertaken in Canada in 1999, MORI's Novartis-funded controversial survey and an equally controversial survey jointly funded by two animal advocacy organisations (BUAV/CWF), both in the UK (Hagelin 2004). On the whole however, consultative activities during this period tended to be quantitative attitudinal surveys and are distinct methodologically from the more deliberative narrative-based methods adopted in a number of exercises during the early 2000s (see below).

The 2000s: With the arrival of the new millennium there is a rapid and fundamental shift in the fortunes of the technology with a cascade of events that ultimately result in the relocation of Imutran from the UK to the US and the scaling down of the Roslin Institute's XTP work. First, the UK government publishes its long awaited report into the BSE/CJD crisis of the late 1990s highlighting a crisis of trust in science and regulation. Secondly, and with a far greater impact on the standing of XTP scientifically, an animal advocacy organisation in the UK releases its report on leaked preclinical trial findings that demonstrate very poor progress in the science. This has a devastating impact on the standing of the field with a rapid impact on policy-making. Regulatory and advisory bodies are quick to dampen the high expectations of the previous year and re-affirm a more precautionary stance. These lowered expectations are present even in the US, where continuing uncertainty concerning the risks of transpecies-infection and the problems of tissue rejection cast doubt upon the future of XTP.

Formal policy-making during this period is scaled-down dramatically in comparison to the previous decade. In fact, there are very few notable policy developments. In 2000, the OECD and WHO jointly publish the outcome of their consultation on XTP biohazard and surveillance insisting on far stronger efforts to control and monitor potential and actual organ and tissue recipients. In the same year Italy, somewhat belatedly, publishes guidelines for applicants who may wish to undertake clinical trials. In 2001 Norway places a legally binding prohibition on XTP (this remains in place until January 2009). In what has been taken as a more telling sign of atrophy in the field of XTP, the UK government disbands its advisory regulator (UKXIRA) in 2006 though this has been criticised for inadvertently weakening

regulatory stringency. A similar move is made by the US, which has in recent years abandoned its specialist advisory body on XTP (SACX).

Whereas the 1990s were characterized by elite policy activity, the 2000s is characterized by a number of more deliberative consultative processes. However, the timing of these, following rather than preceding or running alongside much of the policy activity, can be taken to signal poor prospects for any kind of real and lasting impact. Many, though not all, of these forms of engagement are initiated by academic groups rather than by policy actors. For example, in 2002-3 researchers conduct a 'Neosocratic Dialogue' technology assessment project (XENO) in Germany, Austria and Spain, which is funded by the EU.[1] Additionally, in the early 2000s, two further deliberative studies are undertaken, both led by academics and funded by research councils and charities rather than by policy-makers. Brown and Michael undertake qualitative focus group research, and Davies et al undertake their larger 'deliberative mapping' citizen jury consultation ('addressing the kidney gap'). Though not necessarily directed at addressing XTP specifically, in 2003 the UK government launches its GM-Nation debate, a series of regionally convened opportunities for publics to question expert witnesses and air views. This is widely taken to illustrate recognition of the former disjuncture between government policy and wider public ambivalence.

While the evidence in the majority of the countries reviewed here suggests that deliberative public consultation concerning XTP post-dates substantive regulatory activity, there are also three interesting exceptions to this trend. Of these, Canada provides the clearest illustration of government commitment to the use of public consultation as a basis for the assessment and regulation of XTP. In 2002, a series of regional citizen juries commissioned by the Canadian government recommend that XTP should not be allowed to proceed, and this stance becomes reflected in Canadian XTP policy. In the late 1990s/early 2000s the Swiss government also initiates several technology assessment exercises including a public consultation (in which 28 citizens participate in an event modeled on the Danish 'Consensus Conference') alongside more expert-led events. As in Canada, the outcome of the public consultation seems to feed into subsequent XTP policy. Interestingly, however, the 'public response' and associated policy is entirely different in this context, with Switzerland adopting a *permissive* approach to XTP. This striking divergence points to the importance of comparing the precise dynamics of the consultative and policy-making processes in these two countries. How were the relevant 'publics' constructed and accessed in each case, and what forms of deliberation were they able to engage in? Perhaps more importantly, how was 'the public response' constructed in each case, and by whom?

A third, and slightly less clear-cut, exception to the trend described in this overview is provided by the case of the Netherlands. In the mid to late 1990s, the Dutch government utilizes an expert-led method of assessment to formulate its pro-XTP policy. However, this

[1] See www.ihs.ac.at/departments/soc/xeno-pta/results.html

pro-XTP stance is subsequently criticized in Parliament, by other political parties. This forces the government to commission a public debate (2000-01), which reveals that the majority of the Dutch population do not support XTP research. Although the precise relationship between this debate and the subsequent policy-making process remains unclear, it is notable that the Dutch Parliament went on to implement a ban on XTP.

By way of summary, the timeline presented here documents a clear and evident succession of events that lead from an emphasis on the scientific activity in the early 1990s, to elite-focused expert policy-making in the mid and late 1990s, to a more deliberative consultative focus since 2000. Questions to be taken up in the remaining workpackages and country contexts should focus more on whether and to what extent this broader phasing of the debate applies at a more micro-sociological level.

3.1 XTP – a timeline

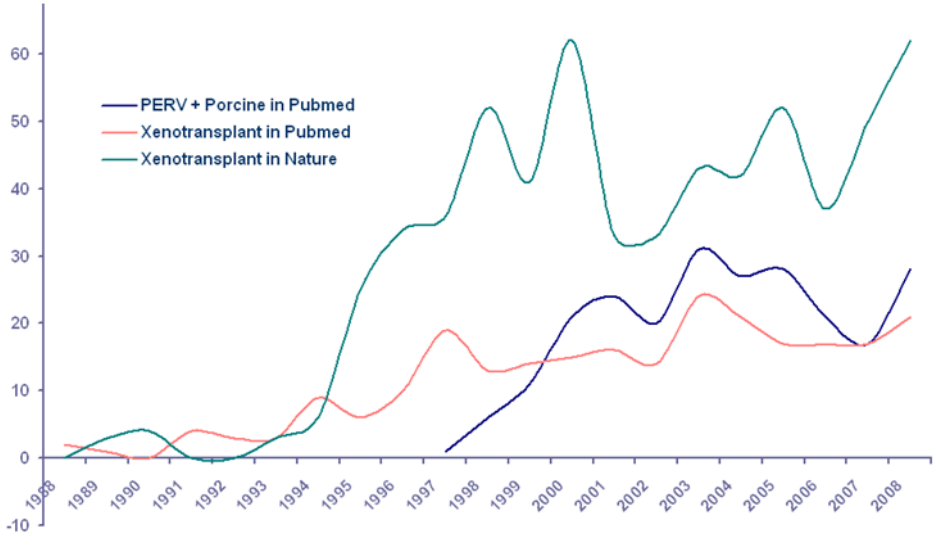

Fig 1 – bibliometric citations in *Nature* and *Pubmed* 1988-2008 (Brown 2009)

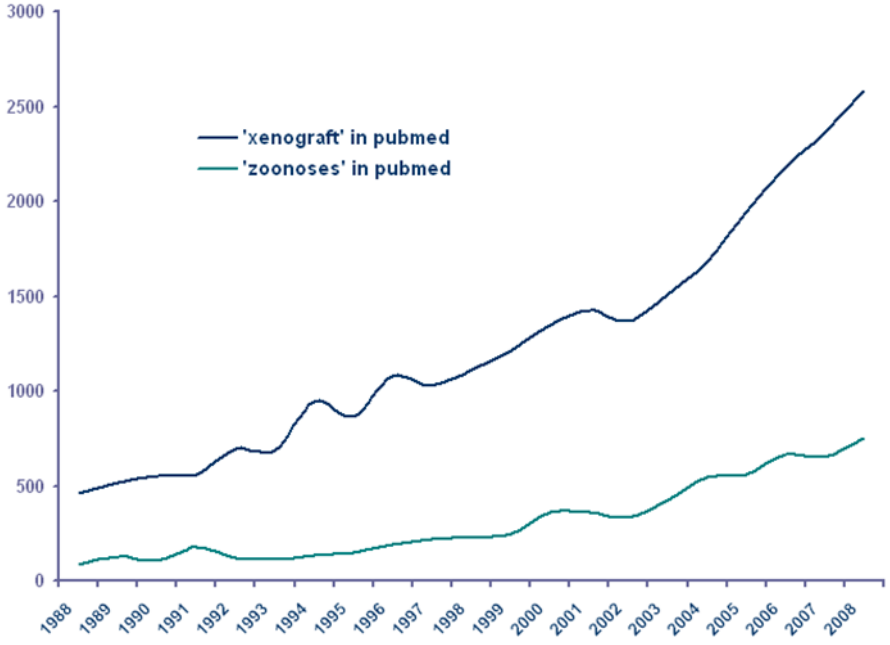

Fig 2 – bibliometric citations for 'xenograft' & 'zoonoses' (Brown 2009)

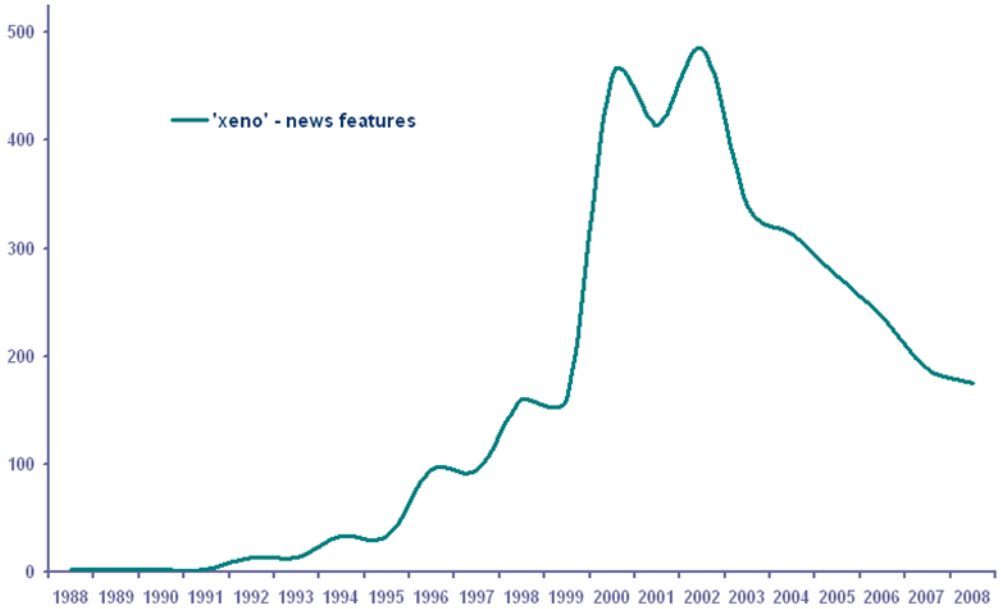

Fig 3 – bibliometric citations for 'xenotransplantation' news features 1988-2008 (Brown

3.2 1980s – Early years

	1979	**1981**	**1984**	**1985**	**1986**	**1989**
EC	*Biosociety* report – biotechnology identified as central in future European competitiveness					
US		CDC Atlanta announces rare immune deficiency disease (HIV)	Baby Fae highly controversial heart transplant from baboon to human infant			
France				HIV first confirmed transpecies link to SIV (simian immune deficiency virus)		
UK					BSE first identified in cattle - the controversy dominates UK science policy into the 1990s	
Poland						– pig to human heart transplantation

3.3 Xenotransplantation enters the European policy agenda

	1990 / 93	**1993**	**1995**	**1996**
Sweden	Clinical trials of porcine islet cells in 10 diabetic patients		Kidney xenoperfusion clinical trial	Commencement of public debate on XTP following parliamentary discussion
UK		Imutran announces the birth of Astrid – transgenic porcine organ source	First CJD death followed in 1996 by gvt admission of probable link	Imutran becomes subsidiary of Novartis The Nuffield Report – invitation to written consultation - advocating a precautionary approach – burden of proof should lie with trial applicants.
US		Starzl transplants 2 patients with baboon livers		Public Health Service agencies produce *Guidelines on Infectious Disease Issues in Xenotransplantation*
EU				ban on all exports of UK beef Biocult survey of 11-18 yr olds in Finland, Germany, Spain and the UK – later expanded to Japan and New Zealand. Funded through the EU's Biotech Programme

	1997	**1998**	**1999**
Sweden	Voluntary moratoria on XTP and the cessation of clinical trials – establishment of the Swedish Committee on XTP	Gene Technology Advisory Board launches a public consultative conference	Swedish Committee on XTP reports
UK	Weiss demonstrates cross-infection between pig and human cells in culture New labour elected – aggressive promotion of industrial bioscience – focus on	Commencement of the public enquiry into BSE/CJD UKXIRA publishes its guidelines on applications to conduct clinical trials	Imutran announces its intention to seek clinical trial approval MORI Poll commissioned by Novartis – contested findings

	1997	**1998**	**1999**
	engagement and building trust The Kennedy Report – Government report – passive invitation to written consultation – more favourable of the technology than the 1996 Nuffield report – recommends the establishment of a statutory regulator. Gvt establishes an advisory regulator: The UK Xenotransplantation Interim Regulatory Authority – mandated to promote dialogue		
US		FDA researchers confirm cross-infection between pig and human cells in culture FDA temporarily halts clinical trials in order to implement new safety criteria	Secretary's Advisory Committee on XTP is established
EU	Moratorium proposed by the Council of Europe		
Denmark			Announcement of work to produce XTP pigs The BIOSAM expert debate on XTP
France		Attitude survey conducted by the National Transplant Agency	French National Ethics Committee publishes its position statement
Netherlands		Health Council backs XTP – calls for public consultation	
Germany	Green party makes statement asking for government clarification on XTP	Gvt TA & academic led quant survey (Schlitt)	
New York		OECD/NYAS expert conference	
Canada	Health Canada National Forum on XTP recommending significant investment in public consultation		Health Canada publishes its draft 'standard' as a basis for evaluating trial applications – undertakes a telephone opinion survey

	1997	1998	1999
Japan			Meeting of the International XTP Association
Norway			Proposes and debates temporary ban on XTP
UK **Germany**		Study identifies PERV in key porcine tissues	

3.4 2000s – A decade of crisis and decline

	2000	2001	2002	2003
Germany	XTP debated in parliament			
Canada	Canada completes large-scale citizen jury regional consultation and presents its recommendations to gvt – recommending that trials should not proceed			
UK	PPL announces the cloning of 5 transgenic pigs BSE/CJD – publication of the BSE/CJD report – highlighting a crisis in trust Uncaged Campaigns leaks Imutran animal experimental data casting doubt on the future of XTP Roslin shuts down its xeno work & Imutran is scaled down & relocated to the US		Brown and Michael – qualitative focus group analysis – Research Council funded	GM Nation Debate – nationwide meetings – generally critical of gvt promotion of the technology Wellcome Trust funded 'deliberative mapping' citizen jury consultation – 'addressing the kidney gap'
OECD	WHO Consultation of XTP Surveillance			
Italy	Regulator publishes guidelines on applications for clinical trials			

	2000	**2001**	**2002**	**2003**
Denmark	Danish parliamentary hearing of the BIOSAM report – XTP to be approved at ministerial level from 2001			
Netherlands	Consultation by the Dutch Consumer and Biotech' Foundation			
Switzerland		'PubliForum' – a government-initiated event modelled on the Danish 'Consensus Conference'		
Norway		Legal prohibition of XTP (in place until 2009)		Establishment of a national XTP committee (periodically reporting in 2004 & 2006)
Japan			Review of public survey data (Macer et al) reveals a widespread lack of trust in the medical profession.	
EU			Eurobarometer Survey	
			EU-funded 'Neosocratic Dialogue' project (XENO) in Austria, Germany and Spain	
Poland				Public survey – showing little support for XTP

	2004	**2006**	**2007**	**2009**
EU	Legislation on medicinal products (Directive 2003/63/EU)			
Italy	Italian referendum on embryo research Attitude survey of Italian university students (Bona et al)	ISMETT – enters $398m deal to sponsor transplant innovation in collaboration with US University of Pittsburgh Medical Centre		ISMETT – US based Revivicor seeks collaborative agreements to set up XTP facilities
UK		UKXIRA is discontinued – authority is devolved to regional ERBs. Gvt criticised for the loss of a centralised regulatory capacity	HFEA public consultation on hybrid embryos – largest such consultation undertaken by the regulator	

4 Concluding discussion – Citizen Participation in science and policy making

At a general level the discussion above raises a wide range of questions about the tripartite relationships between science, policy-making and public consultation or stakeholder involvement:

Instigation? Who it is that is responsible for triggering efforts to generate public debate or discussion is crucial. On the whole, calls by regulatory and advisory agencies for greater public debate failed to be taken up in any significant and meaningful sense. This has not been the case uniformly but rarely resulted in consultative action. With the exceptions of Canada, Switzerland and the Netherlands, most citizen jury style exercises have tended to be academically led and research council/charity funded. The Novartis MORI poll and the BUAV survey both illustrate the impact of sponsoring agencies on representations of 'what the public think' about XTP.

Methodologies of debate? Where policy stakeholders have been responsible for instigating debate on XTP it has overwhelmingly taken the form of quantitative attitudinal surveys. Whilst valuable in their own rights, as instruments of dialogue and deliberation they are inherently limited and are far from ideal forms of mutual learning and engagement.

Timeline? The assessment of whether or not consultation and participation is likely to feed into policy making is fundamentally a temporal question of sequence and succession. The very fact that much of the 'citizenry focussed' activity of recent years postdates actual policy activity points to a significant temporal disjuncture between science, governance and citizen participation. Further questions to be pursued in the country case studies relate to the convergence and interdependence of policy-making at or about the same time. Following from this, what accounts for the relatively sudden cessations in policy and regulatory activity such as that during the early 2000s?

Implied policy and interest preferences? This is a question to be taken up in more detail in subsequent WPs but it is important to ask how XTP is evaluated alongside a broad range of other options or whether choices are limited by, for example, policy preferences and/or industry interests? Whilst some contexts may be more judicial in their approach to policy formation, others may attach greater significance to the appearance of consensus.

Economic and scientific imperatives? All of the countries discussed here are differently configured in terms of their economic, industrial and/or public research investment in biotechnology and XTP specifically. Subsequent WPs will need to ask whether and how these configurations have an impact on policy routes taken and forms of deliberation undertaken.

Political culture? The country overviews presented in the annex to this report highlight the importance of considering questions of regional political culture in the shaping of deliberative debate. Highly federalist cultures, like that of Canada for example, place an obvious premium on the role of consultative practices in managing highly regionalist interests.

Representing publics? It is crucial to establish how and to what purpose survey results and consultative findings are used, and by whom, and to legitimate what kinds of action. In terms of 'impact', this notion of the way 'the public' is used and strategically employed and represented is probably far more significant than stating what it is that 'the public think'.

Impact? Overall, the concept of 'impact' is highly complex and composed of different dimensions and gradations from explicit influence to more general interactions at the level of an intellectual or cultural climate in which decisions are made. Nevertheless, we suggest that there are ways of narrating whether and to what extent policy-making is open to different kinds of stakeholders, at what point in the development of policy and how this process is organised. One possible means of articulating this is in terms of the relative permeability of policy communities, from the impermeable, to relatively porous, to the permeable:

> ***Impermeable*** – This would be characterised by what we might be tempted to call the traditional expert-led 'Westminster model' of elite consultation; often characterised by closed committee hearings; self-selecting participation amongst relatively tight long-established networks; a tendency to privilege technocratic economic and scientific factors; conducted through a highly rationalistic discourse with little room for cultural, historical or reflexive considerations; risk is estimated here with reference to normative cost/benefit calculation; this is a model overwhelmingly vulnerable to capture by ascendant interests.
>
> ***Impermeably porous*** – This probably differs little from the Westminster model but in this case we might see attempts at consultation by means of the production of draft documents and reports for wider stakeholder evaluation. These are often passive acts of public engagement in which one would normally see very little scope for the inclusion of voices beyond directly interested or affected parties. There are few illustrations here of policy-communities actively 'going out', i.e. commissioning deliberative events, etc. Where cultural and historical factors are taken into consideration they are usually authored by moral experts with a bias toward bioethical frames of reasoning. In terms of public consultation, some forms of quantitative attitude surveys may fall into this categorisation. Delphi surveys, foresight panels and open calls for consultation may illustrate an impermeably porous framework of consultation.
>
> ***Permeable*** - Liquid – Relatively new and deliberatively focussed forms of assessment. These are often less constrained and less narrowly defined by focusing

> on a problem at a more general level rather than the narrow and particular. They are problem led rather than solution led. They tend to be qualitative, sensitive to diversity, aspire to inclusivity and transparency. They are dialogic and deliberative attempts at democratic legitimacy through participatory processes with efforts at including seemingly marginal considerations usually ruled out of expert-led practices.

The initial regional and country reviews presented here show very little evidence of permeability in the policy-making landscape as it has applied to XTP over the last two decades. We have discussed and presented some noteworthy exceptions to this and indicated that their benefits were in many cases constrained by the fact that they tend to lag behind policy-making rather than anticipate it.

5 Annex – Regional and Country Reports

5.1 Selected European countries, EU and International Organizations

Authors: Daniel Lehner, Anna Szyma, Erich Griessler, Anna Pichelstorfer

The paper draws on internet research, available literature, grey literature and previous research conducted by the IHS and its partners within the XENO-project.

This paper is meant to give a "helicopter view" on developments in XTP policies and public consultation therein in several European countries as well as international organizations.

5.1.1 Austria[2]

5.1.1.1 Introduction

Austria has no particular XTP policy but some issues which might be relevant for XTP are regulated in the Gentechnology law (GTG).

There is definitely no public debate on xenotransplantation in Austria. The media rarely cover the issue and only a few latent actors are aware of it (Griessler/ Bogner 2003: 5 ff.). No national ethics committee or similar body has provided an opinion on xenotransplantation (European Commission 2001: 4). There has also not been any structured public debate on xenotransplantation up to now. Furthermore, until today, none of the latent stakeholders in xenotransplantation (research, transplantation surgeons, patient groups, animal welfare groups, politics, industry, private and public health insurance) have raised the issue in Austria.

Reports on xenotransplantation in the print media (which is the only public forum on xenotransplantation) are clearly dominated by transplantation surgeons and physicians. If there is any discussion on the ethics of xenotransplantation in the media it is dominated by the positions of the Catholic Church. Secular ethical positions are almost non-existent in the media. Neither are the positions of animal rights activists. In exceptional cases, physicians raise questions of animal rights. Social scientists are not present in the debate. One reason for the dominance of transplantation surgeons in the Austrian xenotransplantation discourse, and for the exclusion of other latent actors might lie in the very lack of controversy on this issue. The discourse focuses on transplantation medicine, and xenotransplantation is a logical step on this trajectory. One of the most striking features is the complete absence of animal welfare groups and environmentalists, which differs from their deep involvement in

[2] This chapter is partly based on the Austrian report of the FP5 funded XENO project: www.ihs.ac.at/departments/soc/xeno-pta/results_1.html download 13.8.09

the debate on genetically modified organisms. Also, patient self-help groups are absent from the debate. Since the Austrian xenotransplantation discourse is in an embryonic state there are no explicit coalitions between actors, but there are surely latent coalitions, e.g. between surgeons, patient self-help groups and pharmaceutical industry on the one side, and animal welfare groups and dissenting natural science and humanities researchers on the other.

5.1.1.2 Overview of landmark developments and timeline/ Key features of policy making and process

Austria has no specific XTP policy and takes a wait and see attitude.

In order to understand Austrian policy in respect to XTP, we have to look at Austrian gene technology policy in general and transplantation policy.

In Austria, neither Parliament nor the Advisory Board on Transplantation at the Austrian Transplantation Co-ordination Organisation[3] have discussed xenotransplantation. Neither has a special public forum been set up so far which could discuss xenotransplantation more deeply. The Advisory Board on Biotechnology at the Federal Chancellery discussed safety questions of xenotransplantation in a general way only and, according to a civil servant in the consumer protection ministry (Federal Ministry for Women's Affairs and Consumer Protection, Bundesministerin für Frauenangelegenheiten und Verbraucherschutz), just very briefly.

No interviewed expert knew of any Austrian forum where xenotransplantation was being debated intensively.

5.1.1.3 Public consultation – and overview / summary of socio-cultural dimensions

The Austrian policy process in general is rather closed, and expert led. Consultation in law making involves mainly experts and established stakeholders (Biegelbauer/Grießler 2009).

By and large political decisions in Austria are made by a small group of actors from politics, administration, established and powerful interest organizations and science or, as a senior civil servant in an interview put it: "you must not forget, decisions in Austria are made by forty people, at the most" (Griessler 2010).

"The" public is little involved in such decisions. In general there were and are few political debates about biomedicine and red biotechnology. This might be connected with a long-

[3] The Advisory Board on Transplantation comprises transplant surgeons, representatives of Austrian federal provinces and local communities as sources of hospital finance, as well as representatives of statutory social and health insurance bodies, of the Ministry of Health, of patients and of the transplantation organisation (Austrotransplant).

standing tradition of paternalistic relationships between state and citizen/public – some keywords in this context are counterreformation, (enlightened) absolutism and neo-corporatism – and a similarly asymmetric relationship between physicians and patients.

In contrast to other European countries in Austria there is almost no independent interest organization of patients. Physicians and the Chamber of Physicians not only act as representatives of their own interests, but also as self-proclaimed spokespersons of their patients (Macheiner 2005). To put it somewhat polemically, Austrian health politics shows some characteristics of 18th century enlightened absolutism, a formative period of the Austrian state (Hanisch 2005, S. 26 ff.). As Braunegger-Kallinger et al. state: "The situation of patients in the last 50 years of Austrian health care can be characterized as being subject to a system of (more or less 'enlightened') paternalism in the health care encounter ('the doctor knows best', 'as much information/participation as absolutely necessary'); (more or less 'enlightened') absolutism (in the tradition of 'Josephinism' in the end of the 18th century) in health policy (decisions are prepared and made by experts who are the only to at least partially understand the rather complex and intransparent system)" (Braunegger-Kallinger et al. 2006: 5).

Two groups of actors outside the direct sphere of politics and administration are playing a particularly important role in the regulation of biotechnology and biomedicine. These groups are experts from science and medicine as well as the Catholic Church. They sometimes disagree in their ethical appraisal of research areas (e.g. in stem cell research, prenatal and preimplantation genetic diagnostics, and in vitro fertilization). Often, however, they are in agreement (transplantation, xenotransplantation, genetic diagnostics in general).

Experts actually have to be considered not only as "impartial" containers of knowledge, but also as stakeholders with privileged access to decision making processes. They act for their own interests and those of their patients (as they perceive them). Scientific experts, physicians in particular, have a great deal of definitional power in the field of biomedicine in Austria. Their well established and assertive organizations are lobbying intensively and are well embedded into processes of policy formulation. As regards red biotechnology and biomedicine a small number of (often identical) scientists and physicians are playing an important role in advisory committees to the Government.[4]

The Catholic Church was and still is a well organized interest organization in Austria. The Church uses formal and informal lobbying in questions of biomedicine and plays an important role in this area. However, concepts that explain the Church's influence mainly via its lobbying might miss the point. Rather, more comprehensive models are necessary which would consider the indirect influence of a Catholic milieu on attitudes and decisions. The

[4] E.g., the Gene Technology Commission and its Scientific Committee for Genetic Analysis and Gene Therapy on Humans and the National Bioethics Committee at the Federal Chancellery.

Catholic Church is not always critical of new technologies. On the contrary, it is often supportive of new methods, e.g. transplantation and XTP.

5.1.1.4 Country chart

Austria	**1990 – 2009**
Principle regulatory Authority	There is no specific regulation that deals with XTP as such. Parts of the subject are regulated in several laws: Procedures for the production of transgenic animals as well as working with the keeping of transgenic animals are covered by the regulations of the Austrian Gene Technology Act (Gentechnikgesetz, GTG 1994). The law is under the competence of the Health Ministry. Transplantation is covered by the Austrian Hospital Act (Kranken- und Kuranstaltengesetz) The Health Minister has an advisory board that consists of three scientific committees advising him/her on matters of genetechnology (Gentechnologiekommission). The national Bioethicscommitttee at the Federal Chancellery did not deal with the matter of XTP.
Principal policy	So far there is no XTP policy in Austria
Public consultations	None
Dominant consultative features	Almost exclusively expert based. Citizen participation plays no role. Impermeable
Key cultural features	Closed political system, in this topic administered by civil servants, little involvement of politicians, heavily expert based, no public debate

5.1.2 Belgium

5.1.2.1 Introduction

Belgium has neither a specific law on XTP nor are there any legislative initiatives discussing this subject. The only legislative procedure in which the term XTP arises has been the

integration of the directive 2003/63 of the European Commission into the law on pharmaceutical products. No public or political debate accompanied this legislative procedure. Although some research in the field of XTP is conducted in Belgium, the topic is not debated in any form within the political community or public media.

5.1.2.2 Overview of landmark developments and timeline/ Key features of policy-making and process

In the survey conducted by the '*Council of Europe*' (2003) Belgium declared that their animal protection laws are applicable in the field of Xenotransplantation (state of 2000). In the same survey Belgium states that it has guidelines for submission of an application to perform xenotransplantation research, although these guidelines could not be found in our investigation. Belgium also declares in this survey that its regulation of XTP is developing towards a two-tier system (governmental and institutional) (Council of Europe 2003). It was difficult to obtain any information about the way in which this regulatory system works in practice. While there is no specific law on XTP, several existing laws are relevant to the regulation of this research:

The law on the protection and good of animals (14 August 1986)

- The adoption of the European Convention for the protection of animals using for medical purposes (Convention européenne sur la protection des animaux vertébrés utilisés à des fins expérimentales ou à d'autres fins scientifiques) (18 Oct.1991)
- The Convention on Biological Diversity during the United Nations Conference on Environment and Development (UNCED), the so-called "Earth Summit", in Rio de Janeiro (Brazil), on 5 June 1992

Belgian regulations on XTP are an application of the EU directives. Because of the federal structure of the country, EU regulations are enforced by the three regional governments (Flanders, Wallonia, Brussels). The three regions have agreed to coordinate their overview of these EU regulations through a common institution: The Institute of Hygiene and Epidemiology (IHE). The EU directives merge into two main laws:

- "Arrêté Royal de 1998 réglementant la dissémination volontaire dans l'environnement ainsi que la mise sur le marché d'organismes génétiquement modifiés ou de produits en contenant" (18.12.98) This law includes the directives 90/220/CEE, 94/15/CEE and 97/35/CE and fixes the conditions for the authorisation of genetically modified organisms. The "Belgium Biosafety Advisory Council" (http://www.bio-conseil.be/) includes experts from the Belgium regions and monitors the procedures.
- "Arrêté Royal concernant les medicaments à usage humain et veterinaire" (14.12.2006) adopts the directive 2003/63 of the European Commission into the law on pharmaceutical products. In a chapter on Xenotransplantation medical products, it

emphasizes the importance of paying specific attention to the "starting material": "Detailed information related to the following items shall be provided according to specific guidelines:

- Sourcing of the animals
- Animal husbandry and care
- Genetically modified animals (methods of creation, characterization of transgenic cells, nature of the inserted or excised (knock out) gene)
- Measures to prevent and monitor infections in the source/donor animals
- Testing for infectious agents
- Facilities
    - Control of starting and raw materials
    - Traceability" (cf. staatsbladclip.zita.be/moniteur/lois/2006/12/22/loi-2006023298.html)

Belgium has xenotransplantation research projects on animal models, but fundamental research is done only in a few university research centers (Nys/Trouchet 2008). There are no industry based projects. Some clinical XTP trials are being undertaken or are planned within the next 3-5 years (ibid.)

In Belgium there are archives of biological tissues, cells or fluid specimens kept on clinical trials involving human beings. There are plans to institute biological specimen archives on either research or clinical XTP protocols in the future. With respect to the scientific perspective, clinical XTP trials are planned or presently underway in Belgium (Council of Europe 2003).

Nys states that there have not been any reactions from any legal authority to the recommendations by the 'Council of Europe' (R 97(15) and 1399(1999)). No discussion has been launched until this day. A legal background is non-existent. Moreover, there have not been any official reactions to international regulations or recommendations. XTP was not a question "*for federal/communitarian parliaments, nor were there any positions, statements or regulations by the National Bioethics Council or any other (non-)official commission*" (Nys/Trouchet 2008: 125). Nys concludes: "If we want to offer sufficient protection for both patients, their relatives, society and source-animals, specific regulation is needed." (ibid: 133) It is unclear if this regulation should take the form of legislation (a new specific law), of an adaption of the law on organ transplantation, or the form of self-regulation by the professional group (Nys/Trouchet 2008).

Although Belgium has a "presumed consent" regulation concerning organ transplantation (similar to, e.g. Austria) the demand for organs is still bigger than the supply. Authorities are

paying attention to the problem of organ shortage and hold campaigns to encourage the population to donate organs. Nevertheless, no information campaigns on XTP, or surveys on the attitudes of the Belgian population towards XTP, have been conducted. Concerning the public, there is a total lack of interest.

The national ethics committee of Belgium (Comité consultatif de Bioéthique de Belgique, NCCB) has not addressed the topic of XTP so far.

5.1.2.3 Public Consultation – and overview/summary of socio-cultural dimensions

We could not find any information on the policy making process, and the legislative adoption of the direction of the EC (2003/63) did not create any political dispute.

We could not find any information on citizen participation in the field of XTP as no policy decisions have been made. There seem to be no stakeholders or pressure groups either.

There has not been any public discussion on XTP or public surveys until now (Nys/Trouchet 2008). Additionally, no information campaigns on XTP have been conducted by the government.

5.1.2.4 Country chart

Belgium	
Principle regulatory Authority	No specific law, based on general norms in the field of GMO
Principal policy	-
Public consultations	-
Dominant consultative features	-
Key cultural features	-

5.1.3 France

5.1.3.1 Introduction

There is little information available on the policy-making process in France. It seems to be expert-led; the public was consulted only once via a survey on attitudes towards xenotransplantation.

Obviously, the French National Transplantation Agency played an important role in discussing the issue in France. Already in 1995 it produced a first draft document on xenotransplantation. Another agency which discussed xenotransplantation and its implications for policy-making was The French National Consultative Ethics Committee for Health and Life Sciences, which recommended a stricter regulation and monitoring than the statement of the Health and Safety Regulation (1998) that xenotransplantation will be regulated by existing biomedical research legislation.

5.1.3.2 Overview on landmark developments and timeline/ Key features of policy-making and process

The French National Transplantation Agency (Établissement Francais des Greffes) was founded in 1994 and was appointed by law for public health and social protection to organize the donation, procurement and transplantation of organs and tissues.

In 1995 the French National Transplantation Agency established an expert commission on xenotransplantation. In 1996, the commission produced a first draft document on "Good Practice Guidelines for the Production of Pigs" (Council of Europe 2003:63).

In 1998 a survey on attitudes toward xenotransplantation was carried out among physicians, nurses, technicians and students on behalf of the French Transplantation Agency. All groups showed support for research on xenotransplantation (Julvez et al. 1999).

In 1998 the French Parliament adopted a draft law on new Health and Safety Regulation, which includes a statement on xenotransplantation. Research on xenotransplantation will be regulated by existing biomedical research legislation. Clinical trials will need the approval of the Ministry of Health and a newly formed health safety agency, “Agence française de sécurité sanitaire des produits de santé” and by the “Établissement français des greffes”. Approval of clinical trials will only be possible after the establishment of a national mechanism for long-term epidemiological surveillance (Council of Europe 2003/Debré 2000/Galloux et al. 2008/OECD).

The French National Consultative Ethics Committee for Health and Life Sciences has produced the document “Opinion on Ethics and Xenotransplantation” in 1999 (French

National Ethics Committee 1999). The committee is not requesting a moratorium on pre-clinical xenotransplantation research. The report states that the use of animals for xenotransplantation is acceptable, but that the views of those who want to protect animals must be respected and that this issue is still under debate. The French National Consultative Ethics Committee concluded that the law is simply a guideline with specific recommendations which do not imply the principle of authorization of xenotransplantation. The committee claimed that the production of xenografts, their use and clinical trials will have to be strictly controlled by legislation and monitored by health authorities. Clinical trials should only be possible after the evaluation of potential risks. The committee called for a broad public debate on xenotransplantation on an international level (French National Consultative Ethics Committee 1999).

In 2006 L'Agence de la Biomédicine has assumed the tasks/functions of L'Établissement Francais des Greffes. L'Agence de la biomédecine combines the four domains of organ procurement, procreation, human embryology and genetics. The Agency has no information on xenotransplantation on its website and hasn't published any reports, recommendations etc. on the topic.

5.1.3.3 Public Consultation – and overview/summary of socio-cultural dimensions

The only consultative exercise was a survey on attitudes toward xenotransplantation that has been carried out among physicians, nurses, technicians and students on behalf of the French Transplantation Agency in 1998. It showed that all groups support research on xenotransplantation and most would accept a xenograft in case of a life-or-death situation (Julvez et al. 1999) after they had received information on xenotransplantation.

5.1.3.4 Country chart

France	**1990 - 2000**	**2006-present**
Principle regulatory Authority	Ministry of Health Agence française de sécurité sanitaire des produits de santé Établissement français des greffes	Ministry of Health Agence française de sécurité sanitaire des produits de santé L'Agence de la Biomédicine (since 2006 instead of L'Établissement francais des greffes)

Principal policy	Permitted - law on new Health and Safety Regulation (1998)	
Public consultations	Survey (1998), Eurobarometer	
Dominant consultative features	Impermeable	
Key cultural features		

5.1.4 Germany[5]

5.1.4.1 Introduction

Germany has a complex, active and multi-faceted xenotransplantation debate that involves different actors from medicine and natural sciences, humanities, policy makers from Parliament, parties and government, as well as NGOs. Hüsing/ Zimmer (2003: 84 ff.) distinguish four clusters:

1. The **transplantation medicine/ natural science cluster** includes the most influential actors and consists mainly of two kinds of actors: (1) scientists and physicians working in transplantation medicine and clinical disciplines and (2) scientists in virology and pre-clinical disciplines. This cluster evolved over time in a difficult and long formation process by settling previously antagonistic views about the infection risk involved in xenotransplantation (Hüsing/ Zimmer 85ff.). At present, this cluster has the strongest impact on the public debate and it sets the agenda in the German xenotransplantation debate. It presents xenotransplantation as a technology-driven solution to the problems of transplantation.
2. The **ELSA cluster** is by far less influential than the biomedicine/natural science cluster. It has less impact on public media and agenda setting. By contrast, it has strong links to NGOs, but these organizations again lack influence and do not participate in the xenotransplantation debate. The ELSA cluster also has limited influence on policy makers, e.g. by TA studies. Despite regular contact during workshops and symposia, the relationship between the transplantation medicine/ natural science cluster and the ELSA cluster is still problematic and mainly antagonistic. The transplantation/ natural science cluster has accepted only a few individuals from the ELSA cluster as equals and has adopted to a limited extent certain thematic and methodological contributions by the latter (c.f. Hüsing/ Zimmer 2003: 87).
3. **Policy makers**. German ministries have so far delegated their participation in international bodies to certain committees and individual scientists from the biomedical/

[5] This part is based on the final report of the XENO project: http://www.ihs.ac.at/departments/soc/xeno-pta/results_1.html download 13.8.09.

natural science clusters. The ministries have privileged access to government owned virology institutes (Paul Ehrlich Institute, Robert Koch Institute), which are part of the transplantation and natural science cluster, but also maintain some contact with the ELSA cluster.

4. **NGOs** cooperate strongly with the ELSA cluster but have no contact with the transplantation medicine/ natural science cluster.

5.1.4.2 Overview of landmark developments and timeline/ Key features of policy making and process

In public administration the Ministry for Education and Research is responsible for xenotransplantation research, the Ministry of Health for clinical application and the prevention and management of potential infection risks. The Ministry of Justice is responsible for legal aspects of xenotransplantation. These ministries give low priority to xenotransplantation and have delegated their seats in national and international committees to individual scientists in the biomedical/natural science cluster (Hüsing/ Zimmer 2003: 58).

In Parliament, the Green Party made a minor interpellation about xenotransplantation in 1997, asking the then conservative-liberal government about its activities in and perspective on xenotransplantation. In its reply the government perceived xenotransplantation as potential medical treatment in the future, but considered clinical xenotransplantation as unjustified for the moment. It believed that genetic modification of animals for xenotransplantation would be justified and thought that xenotransplantation would not impair the identity of humans. It regarded the existing legal framework as sufficient and estimated the federal funds for xenotransplantation research with € 300.000 per year (Hüsing/ Zimmer 2003: 55).

In September 2000, deputies of the Liberal Party in the Bundestag asked the Social-Democrat/Green Party coalition government in a major interpellation about its xenotransplantation position and activities. The answer of the Federal Ministry of Health on behalf of the Federal Government was quite similar to the one given by the former conservative-liberal Government in 1997 (Hüsing/ Zimmer 2003: 58).

The German Bundestag also discussed the recommendation of the Council of Europe, which called for a moratorium. The implementation of a xenotransplantation moratorium in Germany is still pending.

In January 1998 the Parliamentary Committee for Education, Science, Research and Technology Assessment commissioned the Office of Technology Assessment of the German *Bundestag* (Parliament) with a comparative overview on existing TA-studies on xenotransplantation. In summer 1998 the scope of this study was widened to a state of the art report on organ xenotransplantation, a review on the ethical debate about

xenotransplantation and a literature analysis on the legal situation in Germany. All four studies were published, submitted and approved by the contractor in 1999. The Parliamentary Committee for Education, Science, Research and Technology Assessment discussed the report in 2000 in depth and asked the Enquete Commission "Law and Ethics in Modern Medicine" to deal with xenotransplantation. Although the Commission was planning to deal with xenotransplantation it did not have time to do so (Hüsing/ Zimmer 2003: 55 ff.).

As Table 1 shows, several bodies in Germany have produced official papers on xenotransplantation.

Table 1: Summary of selected German xenotransplantation position papers from various actors

Institution	Position	Reference
German Medical Association (Bundesärztekammer) xenotransplantation Working Group of the Scientific Advisory Board	Xenotransplantation is supported in general. Clinical xenotransplantation procedures should not be performed until more information about risks and benefits is available.	Wissenschaftlicher Beirat der Bundesärztekammer 1999
Society for Virology	At the present time, xenotransplantation cannot be considered as an ethically unproblematic alternative to the therapeutic application of human embryonic stem cells. Intensive research is required to reach functionality of xenografts and microbiological safety.	Gesellschaft für Virologie 2002
European Academy for the Study of the Consequences of Scientific and Technological Advances Bad Neuenahr-Wahrweiler GmbH	Cautious and stepwise approach towards clinical xenotransplantation under strictly controlled conditions is recommended. Moreover, strict supervision of xenotransplantation procedures is recommended. Public discussion should be carried out. (Beckmann et al. 2000)	Beckmann et al. 2000
Church Office of the Evangelical Church in Germany, Secretariat of the German Bishops' Conference	Different positions towards xenotransplantation can be taken and are all well founded by arguments. Xenotransplantation is only one of several options to solve the problem of organ shortage. Dealing with this problem must comprise the search for and inclusion of alternatives, other options than xenotransplantation. This research has to orient itself on saving human lives, the dignity of man and respect for animals.	Kirchenamt der Evangelischen Kirche in Deutschland et al. 1998
Institute Technology-Theology-Natural Science	No fundamental ethical objections against xenotransplantation. Research should be supported. Clinical application is rejected for	Haniel et al. 1999

Institution	Position	Reference
	ethical reasons because of uncertainties regarding functionality; compatibility, infection risks and alternative options have not been fully researched. Regulations should be initiated based on interdisciplinary xenotransplantation expert committee.	

(Compiled from Hüsing/ Zimmer 2003)

5.1.4.3 Public consultation - and overview / summary of socio-cultural dimensions

In 2000 social scientists led participatory experiments involving pupils on Xenotransplantation without impact on policy making (Haniel 2002).

Germany has a vivid research scene on the ELSA of xenotransplantation. This ELSA cluster is dealing with xenotransplantation from the perspective of ethics, philosophy, law and an inclusive technology assessment, which involves the above-mentioned aspects in its assessment (Hüsing/ Zimmer 2003: 47 ff.). The ELSA cluster, which is often critical about xenotransplantation, raises issues that the transplantation medicine/ natural science cluster does not deal with. The transplantation medicine/natural science cluster focused on pragmatic solutions to xenotransplantation problems arising from clinical application, stressing the benefit to individual patients. In contrast, the ELSA cluster extended the debate and raised a number of issues not covered by the natural scientists, e.g. acceptability of xenotransplantation as such and in comparison to alternatives, animal welfare, psychology/identity, benefits and risks to the general public, allocation problems on individual, national and international levels, normative questions in law, questions of life and death, the relationship between man and his own body and between man and animals, alternatives to xenotransplantation, social networks in which xenotransplantation evolves, historical and cultural backgrounds of organ transplantation. Some of the actors of the ELSA cluster adopted a problem-driven instead a technology-driven approach (Hüsing/ Zimmer: 47).

Because xenotransplantation is rather far from clinical application it is not a matter of high priority for German patient organisations. In 1998, Schlitt et al. (1999) carried out a survey on German patients waiting for transplantation, which showed that 77 % of patients would accept xenografts.

Animal welfare organisations are very critical about xenotransplantation, but are not involved in the xenotransplantation debate. This may be due to their limited financial and personal resources and their engagement in other campaigns, but certainly also a lack of interest by the media may be responsible for the marginal importance of these groups.

A significant number of German researchers are carrying out xenotransplantation research. Several institutes are studying transplantation, genetically modified animals, islet cell xenotransplantation and infection risks (Hüsing Zimmer 2003: 42 ff).

German xenotransplantation researchers meet in various scientific forums for formal and informal information exchange (Hüsing/ Zimmer 3002: 45 ff.). In brief, the common view in Germany with respect to xenotransplantation research is that xenotransplantation is acceptable in general but should not be practised yet. In the future, xenotransplantation should be controlled via certain prerequisites. Appropriate safety measures and precautions should be developed in order to minimize infection risks for the patient and the general population (e.g. archives of xenotransplant source animal and recipient tissues, registries of xenotransplant recipients, xenotransplant review boards, advisory or supervisory bodies). The individual benefit for xenograft recipients and for the general population must be balanced. Non-human primates should not be used as donor animals, but only in research, as models for humans. Further research is needed on the functionality of xenografts and on microbiological safety. Moreover, it is necessary to develop harmonized international guidelines and regulations for xenotransplantation (Hüsing/ Zimmer: 47).

5.1.4.4 Country chart

Germany	1990 - 2000	2000-present
Principle regulatory Authority	Ministry for Education and Research is responsible for xenotransplantation research Ministry of Health for clinical application and the prevention and management of potential infection risks The Ministry of Justice is responsible for legal aspects of xenotransplantation	
Principal policy	Permitted - law on new Health and Safety Regulation (1998)	
Public consultations	Survey, Social scientists led participatory experiment without	

	impact on policy.	
Dominant consultative features	Impermeable porous	
Key cultural features	Active ELSA research with little influence on policy making.	

5.1.5 Greece

There is no specific legal framework on xenotransplantation in Greece but international regulations are of importance (Caloghirou 2000: 39). In 1998 a new law on allotransplantation was adopted but this law does not regulate xenotransplantation (Canellopoulou-Bottis 2000: 436). Kriari-Catranis concludes that only some of the issues relevant to xenotransplantation are addressed in the Greek legal framework. Because of the new law on allotransplantation the Ministry of Health focused on its implementation and did not address the problems arising from regulating xenotransplantation (Kriari-Catranis 2008: 185).

There has been no public discussion on xenotransplantation in Greece. It has not drawn any attention from the press and no groups or organizations like self help groups or animal rights groups have opposed the development of this technology. The reason for the lack of interest in xenotransplantation could be the absence of knowledge and research on xenotransplants in Greece. Xenotransplantation is not perceived as a subject that could have an impact on peoples' lives (Caloghirou 2000).

5.1.5.1 Country chart

Country Greece	**1990 - 2000**	**2000-present**
Principle regulatory Authority	No one is regulating xenotransplantation	
Principal policy	No specific legal framework	
Public consultations	There have been no public consultations except Eurobarometer	
Dominant consultative features	?	
Key cultural features	No public discussion on XTP; has not drawn any attention from press or groups/organisations	

5.1.6 Ireland

There is no information available on the regulation of xenotransplantation in Ireland. It seems that it was not a subject of high relevance in Ireland.

The Eurobarometer study of 1996 revealed that the two least favoured applications were biotechnology-derived food production and the heterologous introduction of human genes into animals for generating xenotransplant organs (Burke et al.: 59).

The Irish Council of Bioethics has been working on the topics of transplantation and GMOs, but didn't focus on XTP. In August 2005, the Irish Council for Bioethics undertook a nationwide survey to determine the level of understanding, awareness and interest in bioethics amongst the general public. A number of bioethical issues were assessed in detail including: organ donation, stem cell research, patenting, IVF, Forensic DNA databases and end of life issues. As there was no question on xenotransplantation it does not seem to be a subject of high relevance.

The Environmental Protection Agency[6] is the authority in Ireland that implements GMO Regulations, but there was no information on xenotransplantation on the Homepage.

In Ireland Directives 90/219/EEC and 98/81/EC are transposed into Irish legislation through the Genetically Modified Organisms (Contained Use) Regulations 2001 , S.I. No. 73 of 2001.

5.1.7 Netherlands

5.1.7.1 Introduction

Netherlands is an interesting case because it seems that the expert led, proactive approach towards XTP research that was initially taken by Government came under criticism in Parliament. The Parliament demanded a public debate, which was commissioned by the Health Ministry and carried out by the Dutch Consumer Federation with partly unusual participative methods. The debate showed wide skepticism towards XTP research in the Dutch population, and the Parliament (contradicting the Government's previous policy) decided to ban XTP research. It would be interesting to learn if, and in what ways, the outcome of the public debate was reflected in this policy.

[6] http://www.epa.ie/

5.1.7.2 Overview of landmark developments and timeline/ Key features of policy making and process

On December 31,st 1996 the Dutch Minister of Welfare, Public Health and Sport commissioned the Health Council with advice on: "the state of the science and the social and ethical aspects of xenotransplantation" (Akveld/van Maurik 2008: 119). The advisory group was comprised of 19 members including physicians, virologists, molecular biologists, veterinaries, jurists and a representative of the Health Ministry.[7] The aim of the report was to present the scientific status of XTP. The topics which were explored in this paper included possible clinical applications of XTP, ethical questions about XTP and international regulation of XTP in an international context.

In January 1998 the expert group of the Health Council provided a report on XTP (van Rongen 1998). The general tenor of the report was to go ahead with XTP (European Commission 2001: 23 ff.).

Following this report the Dutch cabinet on November 27th 1998 wrote a letter to the Parliament opting for XTP because "the shortage of donors is too high" and alternative treatments would be lacking. Because the interests of patients were considered more important than objections on the grounds of animal welfare, the cabinet did not decide on a prohibition of XTP (Enzing/Kern 2002: 47, Akveld/van Maurik 2008: 121).[8] The cabinet recommends "a policy in which the public is invited to comment on all aspects of xenotransplantation" (Akveld/van Maurik 2008: 122).

On December 13th 1999 the Dutch Minister of Public Health announced in a press conference the launching of a website "Xenotransplantatie, kan dat? (Xenotransplantation, is that to be allowed?) as the first step towards public discussion (Enzing/Kern 2002: 46).

The Dutch government's positive policy towards xenotransplantation met heavy criticism in Parliament.[9] A majority of right wing liberals, Christian democrats and Christian parties urged a de facto moratorium on clinical research and forced the Minister to organize a public debate.

At this stage of the research it is not clear precisely how the results of public consultation entered into and were processed in the political system. However, Dutch XTP policy did make a radical change following the public debate. In February 2000 the majority in the Dutch Lower House opted for a two year moratorium on clinical trials. In 2002 the Lower House voted for a ban on Xenotransplantation (wet op bijzondere medische verrichtingen,

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[7] Contact person for the report was dr. Eric van Rongen, Health Council (e.van.rongen@gr.nl), Tel 031703405730 (European Commission 2001: 21).
[8] Kamerstukken Tweede Kamer 1998-1999, 26335, nr. 1, quoted in (Akveld/van Maurik 2008: 121).
[9] Handelingen Tweede Kamer 1999-2000, p. 3428-3438 and 3587-3589 (quoted in Akveld/van Maurick 2008: 123).

staatsblad 2002, 263). Thus, the Netherlands is one of the few states which have implemented a ban on XTP.

5.1.7.3 Public consultation – and overview / summary of socio-cultural dimensions

Public debate was carried out by the Dutch Consumer & Biotechnology Foundation from November 2000 to April 2001 (Dutch Consumer & Biotechnology Foundation 2001).

A number of conventional and innovative means of communication were used to foster debate: internet websites, public meetings, science theatres, a public survey and a cartoon brochure (Hüsing 2004: 52). Issues debated included general information on XTP, organ shortage, alternatives to XTP to elevate organ shortage, effects on the humanness of XTP patients, animal welfare, the role of politics in decision-making, different standpoints with regards to XTP (Ibid.).

The result of the debate was officially presented in August 2001. The respective report concludes that "The Netherlands is divided about xenotransplantation" (The Dutch Consumer and Biotechnology Foundation 2001: 33). For example, the public survey showed that "23% of the respondents want the government to financially support the development of xenotransplantation. 65% of the respondents are of the opinion that research must not be encouraged" (Ibid.: 32).

5.1.7.4 Country chart

Netherlands	**1990 - 2000**	**2000-present**
Principle regulatory Authority	With regard to preclinical research: Act on experiment using animals (Wet op de dierproven; 1992). Under this Act, an Animal Experiments Committee must give the go-ahead for individual research projects. If genetic modification is involved: the Animal Health and Welfare Act (1996). Biotechnological interventions in animals are forbidden, unless the Minister of Agriculture gives his permission for the protocol in question, after being advised by the Committee on Biotechnology in Animals. With regard to clinical research: Medical Scientific Research Involving Human Subjects Act (Wet Medisch Wethenschappelijk Onderzoek met Mensen; 1998). Research protocols must be reviewed by the Central Committee on Medical Research involving	

	Human Subjects. (c.f. European Commission 2001: 21) XTP. Wet op bijzondere medische verrichtingen; Staatsblad 2002; 2639
Principal policy	Ban on clinical trials
Public consultations	Yes, intense
Dominant consultative features	In the beginning rather expert led, however, public debate seems to have turned around the general policy. Impermeable porous
Key cultural features	Intense public discussion after parliamentary intervention

5.1.8 Poland

5.1.8.1 Introduction

It was very hard to obtain information about xenotransplantation in Poland via the internet. From the limited material available the following short statements can be made.

It is important to keep in mind that Poland after the fall of the communist regime and the accession to the European Union was, and is still, going through a phase of political turbulence with a high number of short lived governments. This, amongst other things, hampers the development of laws regulating biomedicine (Kandic-Popovic 1998).

5.1.8.2 Overview of landmark developments and timeline – Key features of policy-making and process

Transplantation was not clearly regulated by law until March 1996 which brought a wealth of regulations and institutions organizing organ transplantation. The law permitted xenotransplantation in its Article 15.1. stating that “xenotransplantation of animal cells, tissues and organs is allowed for medical purposes”. Art. 15.2. states that “transplantation referred to under Art 15.1, is subject to regulations regarding animal experiments” (Ustawa z dnia 26 października 1995 r. o pobieraniu komórek, tkanek i narządów“ (Dz.U. nr 138, poz. 682).

In July 2005 a new law was enacted that states with regards to xenotransplantation (Ustawa z dnia 1 lipca 2005 r. o pobieraniu, przechowywaniu i przeszczepianiu komórek, tkanek i narządów“ (Dz.U. nr 169, poz. 1411))

Art. 20.1.: Transplantation of animal cells, tissues and organs for medical purposes is allowed.

Art. 20.2.: This transplantation , referred to under Art. 20.1. requires a positive decision from the National Transplantation Council.

Art. 20.3. Transplantation referred to under Art 20.1, is subject to regulations regarding animal experiments

The National Transplantation Council is a statutory advisory body, appointed by the Minister of Health for four years. The Head of the council is appointed by the Minister. The tasks of the council include producing opinions on the requests for xenotransplantation (Art. 41.6. 7). Further tasks of the council are to control the activities and quality of units which are allowed to perform transplantation.

Poland is active in xenotransplantation research. The first clinical xenotransplantation was carried out on December 9th 1989, in which a pig heart was transplanted into a patient who died 24 hours thereafter.

The first experiments with transgenic animals for xenotransplantation were carried out in 1994/1995 (c.f. Przestalksi et al. 118). There seems to be lively and internationally renowned xenotransplantation research in Poland with different research goals, e.g. since the early 2000s a perennial research project started titled “Use of genetic modified pigs to produce organs for transplantation in humans” which produced the transgenic pig TG 1154 (c.f. . Polskie Zrzeszenie Inzynierów i Techników Sanitarnych 2007: 65). Presumably xenotransplantation research in Poland is occupied with this line of research (c.f. Ministerstwo Nauki i Szkolnictwa Wyższego 2007: 13, passim; Smorag et al. 2008).

5.1.8.3 Public consultation – and overview/ summary of socio-cultural dimensions

There seems to be no literature on the political debate about xenotransplantation. The debate in the Second Chamber of Parliament, the Senate, on the 1995 law refers shortly also to xenotransplantation, asking whether xenotransplantation should be regulated within the transplantation law at all and criticizing the fact that Art. 15. does not regulate any details beyond the general permission to conduct xenotransplantation. Moreover it was pointed out that the regulations regarding animal experiments to which Art. 15.3. referred, did not exist at all.

According to a public survey in 2003 conducted by the Biotechnology Committee of the Polish Academy of Science („Komitet Biotechnologii PAN“, http://www.kbiotech.pan.pl/) the Polish public shows little acceptance of xenotransplantation. This result is in line with the Eurobarometer survey in 1998, which showed similar attitudes in the general public (c.f. Fikus 1998). Unfortunately we could not find this study on the internet. The powerful Catholic Church is supportive of transplantation and xenotransplantation. Animal rights activists oppose xenotransplantation (often referring to British groups), but lack public visibility.

There is no information about the processes (closed/participatory) of policy formulation.

5.1.8.4 Country chart

Poland	**1990 - 2000**	**2000-present**
Principle regulatory Authority	Law on transplantation (1996) Xenotransplantation requires a positive decision from the National Transplantation Council (advisory body appointed by the Minister of Health)	
Principal policy	permtted	
Public consultations	public srvey in 2003	
Dominant consultative features	?	
Key cultural features	?	

5.1.9 Portugal

Portugal has no specific law on XTP and there have been no public discussions or surveys on XTP. In Portugal clinical trials involving human beings have not been done to date. Before further steps are taken, a regulatory framework is necessary, because the current regulation addresses only some of the issues relating to XTP (Pereira de Melo 2008: 43). A new regulation has to consider the following laws (see Homepage of Xenome Project[10]).

Collection and transplantation of organs and human tissues

Law(12 / 93, 22.April)

Portaria 31/2002, 8 January

Clinical(Trials)

Decree 97/95. 10. May (Ethical Commissions)

Law(46 / 2004, 19.August)

Portaria 57/2005, 20. January (Ethical Commission for Clinical Investigation CEIC)

National Council of Ethics for Life Sciences

Law 19/90, 9. June (modified by Law 9/2003, 13. May)

Law 6/2004, 26. February and Decree 193/99, 7. June

[10] http://www.xenome.eu/legal_framework_xenotransplantation.aspx?fr=portugal#salto

Law of Transplants

Law(12 / 93, 22.April)

Decree 244/94, 26. September (National Registration of non-donors)

Use of dead bodies for education and scientific investigation

Decree(274 / 99, 22.July)

Certification of death

Declaration of 1. September.1994, by the Medical Association

Animal(Protection)

Law 92/95, 12. September (modified by Law 19/2002, 21. July)

Law(141 / 99, 28.August)

Animal protection when used for experimental and other scientific purposes

Decree 129/92, 6. July (modified by Decree 197/96, 16. October)

Portaria 1005/92, 23. October (modified by Portaria 466/95, 17. May and Portaria 1131/97, 7. November)

Genetically modified organisms

Law(12 / 2002, 16.February)

Decree 72/2003, 10. April and Decree 164/2004, 3. July

Decree 36/2006, 20. February (cross border transportation)

Biotechnology(inventions)

Article 63 of Code for Industrial Property (approved by Decree 36/2003, 5. March)

Regulation for the Scientific Institutions

Decree Law 125/99, 20. April

5.1.10 Switzerland

5.1.10.1 Introduction

Switzerland is an interesting case for our research since Swiss researchers were not only active in XTP research, but the Swiss Government also commissioned several expert led and participatory TA processes which finally resulted in a permissive XTP policy. Switzerland is a particular interesting case of a country with a long and outstanding tradition in direct democracy. We therefore suggest including Switzerland into our country sample for in-depth analysis. This would expand the number of cases of countries with PTA in XTP (Canada, Netherlands, Denmark).

5.1.10.2 Overview of landmark developments and timeline/ Key features of policy making and process

There was public discussion (Die Bundesversammlung 1996, SAMS 2001) of XTP in the political domain in the context of formulating a new Transplantation law (Bundesgesetz über

die Transplantation von Organen, Geweben und Zellen). Several TA Studies were carried out by Fraunhofer Institute, Karlsruhe, which were expert led, but also included some attempts to try and involve stakeholders (Hüsing et al. 1998, Hüsing et al. 2001). In addition, public consultation was carried out (see below). It seems that these results also have been considered in political decision making (Eidgenössisches Department für Inneres 2001, Seebach 2001). The discussion took several years and the Transplantation law came into force in 2004.

5.1.10.3 Public consultation – and overview / summary of socio-cultural dimensions

TA-Swiss, the Swiss National Science Foundation and the Federal Health Department organized a so called PubliForum in 2001. The PubliForum was modeled after the Danish Consensus Conference and involved 28 citizens who discussed the issue on several weekends and at a public hearing and produced an opinion. The majority of the PubliForum opted against a moratorium on XTP research and also the Transplantation law does not include such a clause. Research has to be registered with the Swiss Health Department (Eidgenössisches Departement für Inneres 2007).

5.1.10.4 Country chart

Country	**1990 - 2000**	**2000-present**
Principle regulatory Authority	Health Department (Eidgenössisches Department für Inneres)	
Principal policy	Research permitted, research has to be registered with the Swiss Health Department	
Public consultations	PubliForum	
Dominant consultative features	Expert led TA studies with consultative elements, citizen conference (Publiforum), Permeable	
Key cultural features	Strong federalism and strong elements of direct democracy	

5.1.11 Other European Countries

For **Bulgaria, Cyprus, Czech Republic, Hungary, Latvia, Malta, and Slovak Republic** some information on the regulations in 2000, or regulatory efforts planned from 2000 onwards, could be found in a survey conducted by the Council of Europe (Council of Europe 2003).

In 1999 the Working Party on Xenotransplantation, set up within the Council of Europe, prepared a questionnaire which was sent to 27 states to get an update on the regulatory as well as scientific developments in XTP. The survey showed that there is no legal framework specific to xenotransplantation in Bulgaria, Cyprus, the Czech Republic, Hungary, Latvia, Malta, and the Slovak Republic.

The contact person from **Bulgaria** states that xenotransplantation research cannot be carried out without requesting specific authorization from a regulatory board or government body and that an authorization is required for xenotransplantation research in the case of animal xenotransplantation protocols. Bulgaria has guidelines for submission of an application to perform xenotransplantation research.

Cyprus specified that xenotransplantation research cannot be carried out without requesting specific authorization from a regulatory board or government body and that an authorization is required for xenotransplantation research in the case of animal xenotransplantation protocols.

The contact person in the **Czech Republic** answered that their animal protection laws are applicable in the field of XTP, but the Czech Republic did not have regulations in place covering clinical or experimental XTP. But it also states that XTP research cannot take place without an authorization by a regulatory board or government body. The Czech Republic has a transplantation law (285/2002 and following directives 436/2002, 437/2002), but it does not cover XTP (according to the translation provided by the Ministry of Health of the Czech Republic in the WHO International Digest of Health Legislation[11)].

Hungary specified in a survey in 2000 that xenotransplantation research cannot be carried out without requesting specific authorization from a regulatory board or government body (Council of Europe 2003: 76ff). But in 2000 it had no legal framework specific to xenotransplantation. According to the OECD country profile[12] the responsible agency for regulating XTP in Hungary is the Ministry of Welfare, human health care and medicine production and the Ministry of Industry, Trade and Tourism. Relevant laws are ACT No. XXVII of 1998 on biotechnology activities and Decree No. 1/1999 (I.14.) FVM on the implementation in the agriculture and food-industry of the rules of the Act No. XXII of 1998 on biotechnology activities.

The contact person in **Latvia** answered that XTP research cannot take place without authorization by a regulatory board or government body. The survey showed that there are government controls with respect to pharmaceutical or industrial xenotransplantation

[11]http://apps.who.int/idhl-rils/results.cfm?language=english&type=ByVolume&intDigestVolume=53&strTopicCode=IVC
[12] http://www.oecd.org/document/25/0,3343,en_2649_34537_1888025_1_1_1_1,00.html

research. The contact person also stated that there have been public surveys and that (in 2000) there were plans for a public discussion.

No information could be found on the regulations in **Malta**. The survey showed that there are plans for a public debate relating to xenotransplantation , and that initiatives for such public debate have already begun (Council of Europe 2003: 76ff).

The **Slovak Republic** has few regulation procedures concerning xenotransplantation (McLean/Williamson 2003: 137). In the survey conducted by the Council of Europe the Slovak Republic stated that an authorization is required for xenotransplantation research in the case of animal xenotransplantation protocols, that its animal protection law is applicable in the field of Xenotransplantation and that it has developed measures in the event of a cross species infection or a xenozoonosis epidemic. It declared that there are plans for public debate relating to xenotransplantation and there is an existing or planned registry of xenotransplantation protocols.

We did not find any information at all for **Estonia**, **Lithuania**, **Slovenia**, or **Romania**. There is no information about the regulation of XTP on the Xenome-Homepage or the OECD Homepage, Council of Europe, or EU. No information could be found in the Journal *Xenotransplantation* or on the internet.

5.1.12 European Union

5.1.12.1 Introduction and Methods

Different international organizations have discussed Xenotransplantation during the 1990ies. The Council of Europe, the WHO and the OECD have published opinions, statements or guidelines concerning xenotransplantation, but none of them were legally binding. Yet, at EU level there are legally binding provisions (Straßburger 2008). There are three forms of binding legislative acts the Union can pass: a regulation, which is a directly applicable law; a directive, which constitutes a framework of objectives which a national law must be based on to meet the stated aims; and a decision which applies only to a particular issue.

5.1.12.2 Overview of landmark developments and timeline – Key features of policy-making and process

In 1999 the Scientific Committee on Medicinal Products and Medical Devices (SCMPMD)[13], which was established in 1997 as one of three advisory Scientific Committees working in the

[13] The Scientific Committee on Medicinal Products and Medical Devices (SCMPMD) – amongst other scientific committees established by the Commission - has come to an end by 2004/210/EC Commission Decision of 3 March 2004 setting up scientific committees in the field of consumer safety, public health and the environment. The following scientific committees were established instead: the Scientific Committee on Consumer Products (SCCP),

fields of consumer safety, public health and the environment to provide the Commission with scientific advice in the respective fields, discussed Xenotransplantation amongst other issues of importance for public health. The SCMPMD felt a need to establish a working group to identify issues that may require regulation/ community wide action as the first steps in xenotransplantation had already been taken.

Meanwhile, in 2001 Directive 2001/18/EC on the deliberative release into the environment of genetically modified organisms established legal provisions, although it did not directly address xenotransplantation (Cozzi et al. 2009). Also in 2001, Directive 2001/20/EC relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use had been established. This Directive (updated by Commission Directive 2005/28/EC) was of importance as it explicitly addressed the use of xenogeneic cell therapy. For each clinical trial, approval is mandatory and the authorization by competent authorities must be completed within 60 days, a period that can be extended by 30 days or more in the case of gene therapy products. In the case of using xenogeneic cells, there shall be no limit to the authorization period and a written authorization is necessary before commencing the trial.

The discussions by the established working group on xenotransplantation resulted in an "Opinion on the State of the Art Concerning Xenotransplantation" (SCMPMD 2001) which was reported to the Directorate General for Health and Consumers (DG SANCO) of the European Commission and published in 2001. It identified Directive 2001/20/EC as a possible legal framework for regulation of clinical trials involving xenotransplantation. The following recommendations were established (Hüsing 2004):

- The European Commission should propose the establishment of a centralised regulatory body to oversee the process and to minimise the risks,
- the European Commission should carry out a thorough and ongoing risk analysis of XTP on the basis of the results of both research and clinical trials,
- specific measures for clinical trials dealing with authorisation, informed consent, registration, surveillance of patients and those at risk should be defined on the basis of Directive 2001/20/EC,
- appropriate quality requirements related to health status, animal welfare and animal production should be defined and implemented for the XTP source animals,
- appropriate quality requirements for procurement of organs and their clinical use should be formulated and implemented for centres performing XTP,

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the Scientific Committee on Health and Environmental Risks (SCHER) and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR).
From March 2009 three newly established scientific committees have taken up the task of SCCP, SCHER and SCENIHR: the Scientific Committee on Consumer Safety (SCCS), the Scientific Committee on Health and Environmental Risks (SCHER) and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR).Members of these Committees are appointed by the Commission

- requirements for surveillance should be defined and implemented for the source animals, XTP recipients and others at risk,
- the European Commission should stimulate and support research on detecting and understanding the risks of viral infections with respect to XTP, and the risks associated with severe immunosuppressive drug therapy, especially relating to interference with other drug therapy.

Also in 2001, Directive 2001/83/EC on the community code relating to medicinal products for human use was established. After being amended by Directive 2003/63/EC regulatory oversight on xenotransplantation in the field of medicinal products had been established by including xenogeneic cell therapy into the Annex I (Part IV) to the EU directive of medicinal products.

In 2002 the use of xenogeneic cell therapy medicinal products was discussed at the European Medicines Agency (EMEA) expert meeting on “Xenogeneic Cell Therapy”. The discussion resulted in the document “Points to Consider on Xenogeneic Cell Therapy Medicinal Products”, which was elaborated by the Committee for Proprietary Medicinal Products (CPMP) and entered into force in June 2004 . It lays down some principles that can be used if a marketing authorization application for a xenogeneic cell therapy product is developed for submission to regulatory agencies within the EU. The documents also points out that these guidelines should not be considered as a promotion of clinical trials including animal cells.

End of December 2008 a new regulation (Regulation 1394/07) on advanced therapy medicinal products (ATMP) came into force. It is amending Directive 2001/83/EC and Regulation 726/2004/EC. Advanced therapy medicinal products include gene therapy, somatic cell therapy and tissue engineered products. This regulation established provisions for placing viable cell-based and tissue-based products for human use on the market (Tallacchini/Beloucif 2009). Regulations for cell-based therapies and tissue-engineering products have been developed separately from xenotransplants, but by passing Regulation 1394/2007 the European Union has one single regulatory provision that covers all ATMP (human and animal). A centralised marketing authorization, once granted by the European Commission, is valid in all European Union (EU) and EEA-EFTA states (Iceland, Liechtenstein and Norway). This centralized authorization procedure was installed through the Committee for Advanced Therapies (CAT) within the EMEA. The main responsibility of the CAT is to prepare a draft opinion on each ATMP application submitted to the European Medicines Agency, before the EMEA’s Committee for Medicinal Products for Human Use (CHMP) adopts a final opinion on the granting, variation, suspension or revocation of a marketing authorisation for the medicine concerned.

Another topic that had been widely discussed over the last years was the use of non-human primates for experimentation which is relevant in the field of xenotransplantation

(Tallacchini/Beloucif 2009). In 2007 the Commission was asked by the European Parliament (after reports by Animal Defenders International, National Anti-Vivisection Society and Lord Dowding Fund for Humane Research) to stop experimentation on non-human primates and responded that establishing a timetable for replacing the use of primates in scientific experiments with alternatives is not yet possible. The Commission then requested an opinion in this context from the Scientific Committee on Health and Environmental Risks (SCHER) in order to participate in the discussion. The opinion was provided by an expert group. It was published and open for comments from stakeholder in May/June 2008. SCHER has undergone a public hearing with stakeholder representatives with scientific expertise in November 2008.

5.1.12.3 Public consultation – an overview / summary of socio-cultural dimensions

There was no public consultation. Instead, experts were involved in different scientific committees, working groups or via comments on documents in a public hearing.

5.1.12.4 Chart

EU	
Principle regulatory Authority	European Medicines Agency Committee for Medicinal Products for Human Use (CHMP) adopts a final opinion on the granting, variation, suspension or revocation of a marketing authorisation for the medicine Since 2007: Committee for Advanced Therapies (CAT) submits a draft opinion to CHMP
Principal policy	Permitted, clinical trials and xenogeneic cell-based medicinal products have to be authorized
Public consultations	No public consultations
Dominant consultative features	Expert consultations, stakeholder (with scientific expertise) dialogues
Key cultural features	

5.1.13 Council of Europe

The Council of Europe (CoE), founded in 1949 and comprising today of 47 countries, is besides the European Union one of the two major trans-European political structures (Council of Europe 2010a). The CoE's objective "is to create a common democratic and legal area throughout the whole of the continent, ensuring respect for its fundamental values: human rights, democracy and the rule of law" (Council of Europe 2010b).

In the area of health the CoE wants to promote a health policy "with an emphasis on fusing the agendas on human rights, social cohesion and health leading to a harmonization of the health policies of Member states with regard to safety and quality as well as developing prevention and health education" (Härtel 2003: 53).

In order to reach these goals the CoE has two instruments at its disposal, Conventions, which are legally binding for the Member states which have signed them and Recommendations, which are not of legally binding character (ibid.).

The CoE has two bodies, the Committee of Ministers comprising of the Ministers of Foreign Affairs of all Member States or their respective representatives as well as the Parliamentary

Assembly, a body of more than 300 delegates consisting of 2 to 18 delegates from each Member country (ibid).

In dealing with the topic of xenotransplantation the Council of Europe refers inter alia to the following fundamental policy documents: (1) The "Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine", the "Additional Protocol Concerning Transplantation of Organs and Tissues of Human Origin"; (3) the "European Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes" (see, e.g., Melo et al. 2001).

Already on 30 September 1997 the Committee of Ministers recommended its Member states in order to minimize "risk of transmission of known or unknown diseases and infections to either the human or animal population" to "establish mechanisms for the registration and regulation" of "(i.) basic research and clinical trials" of XTP, "(ii.) the source and care of animals for use in xenotransplantation, (iii.) xenotransplantation programmes; (iv.) long term follow up and review of xenograft recipients and the xenograft source animals" (Council of Europe 1997).[14]

The Committee on Science and Technology (Council of Europe 1998) referred to this Recommendation and asked in a Draft Recommendation adopted by this Committee on 23 June 1998 with two abstentions for "the rapid introduction in all member states of a legally binding moratorium on all clinical xenotransplantation" and to "take steps to make this moratorium a world-wide legal agreement" (ibid.). Rapporteur of the Committee on Science and Technology was Gian-Reto Plattner, a Swiss Parliamentarian of the Socialist Group who also initiated this motion (see: Neue Zürcher Zeitung 1998, Plattner 1999a). This Draft Recommendation went beyond the Committee of Minister`s document and required a complete stop of xenotransplantation research until more knowledge about the risk of this technology were available. In his explanatory memorandum the rapporteur, Gian-Reto Plattner, stated that there are "important ethical as well as legal and social aspects that need to be analysed and debated" (Council of Europe 1998). He criticized a "lack of public debate on xenotransplantation" (ibid.) and called for "a public debate" (ibid.). The draft Recommendation was submitted to the Parliamentary Assembly on 9 July 1998.

On January 29th 1999 the Parliamentary Assembly unanimously (Plattner 1999) adopted the Draft Recommendation as its Recommendation No. 1399(1999). It recommended to the Committee of Ministers to (i.) work for the rapid introduction in all member states of a legally-binding moratorium on all clinical xenotransplantation", (ii.) "take steps to make this moratorium a worldwide legal agreement; (iii.) ask its European Health Committee and

[14] For a short overview on the CoE's activities in the area of regulating xenotransplantation see Härtel 2003 and Simon 2008: 39-44.

Steering Committee on Bioethics to work out, in cooperation with the World Health Organization, a strategy for balancing the ethical, medical, scientific, legal, social and public health aspects of xenotransplantation, before the scientific and medical establishment is permitted to proceed with clinical trials on humans" (Council of Europe 1999a). The decision was criticized by supporters of clinical trials, e.g. the later Vice-President of the Working Group of Xenotransplantation Didier Houssin and a Novartis speaker (Butler 1999: 281) but also Spanish xenotransplantation researchers and the Spanish Government (Bosch 1999).

The Committee of Ministers did not take a position on this unanimous call for a moratorium of clinical trials by the Parliamentary Assembly but installed a "Working party on Xenotransplantation" comprising of twelve members, all of them experts, from such diverse fields as ethics, law, medical research, clinical practice, epidemiology, immunology and animal protection.[15] The Working Party was under joint responsibility of the Steering Committee on Bioethics and the European Health Committee (Council of Europe 2000: 1). The group met from 1999 to September 2001 (Council of Europe 2003: 7, Härtel 2003), delivered its first interim report in July 2000 (Council of Europe 2001)[16] and its final report in February 2003 (Council of Europe 2003a). It also drafted guidelines that were approved by the Steering Committee on Bioethics and the European Health Committee and later by the Committee of Ministers (Council of Europe 2003b, 2003c).

In contrast to the Parliamentary Assembly, which asked for a moratorium, the Recommendation of the Working Party was "an extremely precautionary approach that could nevertheless allow certain clinical trials to proceed under very strict conditions" (Härtel 2003: 54). The Recommendation provided that XTP should only be carried out in countries that provide regulation of XTP according to the Council of Europe's provisions. These included, e.g., authorization of centers; accreditation of competent teams; plans for public health protection and tractability; implementation of quality assurance mechanisms; information of patients and close contact persons; specific, free and informed consent of patients; counseling of patients and protection of source animals. Moreover, member states should stimulate public discussion on XTP and cooperate internationally (Council of Europe 2003b, 2003c).

Central features of the policy process within the Council or Europe were that the issue of xenotransplantation was taken up quite early by both of its bodies, the Parliamentary

[15] „The Working Party was Chaired by Mr. Bart Wijnberg (The Netheralands) and was composed of Prof. Didier Houssin (Vice-Chair, France), Prof. Annika Tibell (Vice-Chair, Sweden), Prof. Pekka Häyry (Finland), Prof. Karin Ulrichs (Germany), Dr. Marialuisa Lavitrano (Italy), Dr. Dag Sorensen (Norway), Prof. Alexander Tonevitsky (Russian Federation), Dr. Rafael Manez (Spain), Dr. Theodor Weber (Siwtzerland), Dr. David Cook (United Kingdom), Dr. Maggy Jennings (United Kingdom) and Dr. Line Matthiessen (European Community)" (Council of Europe: 7). Moreover representatives from United States, Canada and organizations such as the International Xenotransplantation Association, OECD, Office International de Epizootes and WHO were present as observers (ibid.).

[16] For an overview see: Paslack 2008: 124-130, for an overview on the Draft Recommendation see Härtel 2003.

Assembly as well as the Committee of Ministers. Both institutions issued legally non binding recommendations. However, whereas the Parliamentary Assembly took a radical restrictive stance, demanding a moratorium on clinical trials, the Committee of Ministers took a permissive position and finally agreed on continuing clinical research provided that Member States meet certain conditions. Though the need for public discussion of xenotransplantation was often expressed in various documents (De Sola 1998: 212 pp., Plattner 1999b: 34, Wijnberg/Houssin 2001, Council of Europe 2003b: Preamble and Article 30) the CoE actually seems to have made no attempts to fulfill its own claim. Härtel (2003), e.g. states, that the presentation of the Recommendation to the Parliamentary Assembly should to some degree "satisfy the demand for sufficient public debate" (2003: 55). Also the composition of the Working Group on Xenotransplantation - all members were experts without a representative of "the" public - showed impermeability in policy making. There seems to be no policy development after 2003.

5.1.13.1 Chart

Council of Europe	**1990 - 2009**
Principle regulatory Authority	Committee of Ministers, Parliamentary Assembly, Steering Committee on Bioethics and the European Health Committee, Working Group on Xenotransplantation,
Principal policy	Permissive after fulfilling a number of prerequisites
Public consultations	None
Dominant consultative features	Though several calls for public debate consultative features exclusively expert based, Impermeable. Citizen participation plays no role.
Key cultural features	Closed political system, heavily expert based, no public debate

5.1.14 OECD

5.1.14.1 Introduction

The Organisation for Economic Co-operation and Development (OECD) has addressed the issue of XTP within its activities related to scientific, industrial and health applications of biotechnology. It provided background papers and held expert consultations. The main focus was to provide an overview of the scientific progress in xenotransplantation, to discuss

ethical and socio-economic issues and the need for international cooperation. The OECD provided an overview on XTP regulation in different OECD member states and discussed together with the WHO the development of global standards for surveillance of the import/export of transgenic animals or organs and of recipients of xenografts.

The activities of the OECD in the field of xenotransplantation seem to have stopped after 2001. No reports were published afterwards.

5.1.14.2 Overview of landmark developments and timeline/ Key features of policy making and process

In 1996 Elettra Rochi wrote a background paper in preparation for an OECD workshop on xenotransplantation (OECD 1996). Issues raised by the report were: the problem of organ shortage, immune response, immunosuppression, the risk of infection and the question of whether to use primate or porcine organs and tissue. The focus was on economic questions, e.g. if xenotransplantation would be cost-effective. Xenotransplantation was perceived as a useful method, but one which should be discussed and regulated at an international level. It was suggested that the WHO could coordinate international efforts concerning the regulation of the safety of xenotransplantation. The OECD could focus on the discussion of ethical and socio-economic aspects at an international level (Paslack 2008: 116).

In 1998 the OECD and the New York Academy of Sciences (NYAS) organized in New York the “International Workshop on Xenotransplantation: International issues in transplantation biotechnology including the use of non-human cells, tissues and organs”.[17] This conference was attended by 150 experts and delegates of OECD countries, Israel, the Cameroon, the Sultanate of Oman and the European Commission. The aim was to discuss the scientific progress, but also to facilitate international co-ordination and co-operation. Because of the international implications of xenotransplantation, researchers, clinicians, regulators, ethicists, advocates, legal experts, and economists from various countries came together to develop a common understanding of the benefits and risks associated with xenotransplantation.

A report summarizes the main issues discussed at the workshop (OECD 1999b). Xenotransplantation is seen as a useful tool to improve the quality of patient lives if certain criteria are fulfilled: reducing the risk of infection, resolving immunological and physiological barriers, protecting the patients, and guaranteeing animal welfare. The workshop participants stressed the importance of an international approach to risk management of infections, registries for xenorecipient surveillance and guidelines for research and animal husbandry. It was argued that international discussion should be co-ordinated by the OECD and WHO and should include a number of key players (industry, medical community, public health and legal experts, veterinary surgeons and experts in animal husbandry, policy makers, patients’

[17] Information about the Conference and a list of participants can be found on: http://islet.org/34.htm (Accessed 30 September 2009).

associations and ethics experts). The need for an international co-operative resource to keep records on xenografts and information on guidelines and regulatory issues was expressed.

In October 2000 the OECD/WHO Consultation on Xenotransplantation Surveillance took place (OECD/WHO 2001). The report summarizes the main discussion points. Countries willing to conduct clinical trials should establish a national surveillance system. Besides the national surveillance systems an international system is necessary. The participants agreed that existing surveillance systems and tools should be used and the WHO, together with the OECD and other relevant international bodies, should take a leadership role in establishing an effective international surveillance network. The report notes that ethical guidelines currently in place do not cover all the relevant issues raised by xenotransplantation and should be further developed and publicly debated.

The OECD provides on its homepage a compilation of regulatory developments in xenotransplantation in OECD Member States, status year 2001.[18]

5.1.14.3 Public consultation – and overview / summary of socio-cultural dimensions

There was no public consultation. The consultations were expert-led.

5.1.14.4 Chart

OECD	**1990 - 2000**	**2006-present**
Principle regulatory Authority	National Countries	
Principal policy	Permitted	
Public consultations	None	
Dominant consultative features	Expert-led; Impermeable	
Key cultural features	Expert organisation with strong political ties.	

[18] http://www.oecd.org/countrylist/0,2578,en_2649_34537_1783767_1_1_1_1,00.html, download: 14.08.09.

5.1.15 WHO

5.1.15.1 Introduction

The World Health Organization (WHO) was one of the first international organizations to deal with xenotransplantation and has addressed this issue several times over the last few years (Hüsing 2004). The WHO conducted expert consultations, launched an internet electronic discussion group on xenotransplantation and an Inventory of human xenotransplantation practices. The focus of these consultations was mainly on the prevention and management of the risk of infection. The WHO published several reports, guidance and recommendations and calls for national regulation in nations where clinical trials are conducted. The WHO urges its member states that research in xenotransplantation or clinical trials should only be allowed if strictly regulated. Furthermore, an international surveillance system should be established. Besides focusing on the risks, the WHO also discussed ethical issues, mainly the protection of patients and the protection of public health. The WHO consultations did not involve citizens.

5.1.15.2 Overview of landmark developments and timeline/ Key features of policy making and process

In October 1997 the World Health Organisation (WHO) held a consultation on xenotransplantation which resulted in a report (WHO 1998a). The focus was on risk management but ethical and social considerations were also taken into account. The report gives recommendations to WHO member states and to the WHO in order to help them deal with xenotransplantation, they "*are not meant to encourage or discourage early clinical trials, but rather to call attention to the issues that need to be taken into account by countries considering the adoption of this technology*" (WHO 1998a: 10). Besides national policies the report calls for international coordination to "*help promote saftey, efficacy and equitable access to the technology*" (WHO 1998a: 10).

In 1998 the WHO published another document, a "*Guidance on Infectious Disease Prevention and Management*" (WHO 1998b), which addresses the risks of infection and concentrates on the question of how to prevent the spread of infectious diseases. The authors assume that xenotransplantation will become medical practice; therefore they offer recommendations on how to minimize risks for public health.

In 1999 the WHO launched an internet electronic discussion group on xenotransplantation policy (Birmingham 1999).

In October 2000 a consultation on xenotransplantation surveillance was held together with the OECD which was attended by over 60 experts in the field of XTP (WHO 2001a). The report summarizes the main discussion points. Countries willing to conduct clinical trials

should establish a national surveillance system. Besides the national surveillance systems an international system is necessary. The participants agreed that existing surveillance systems and tools should be used and the WHO, together with the OECD and other relevant international bodies, should take leadership in establishing an effective international surveillance network. The report notes that ethical guidelines currently in place do not cover all the relevant issues raised by xenotransplantation and should be further developed and publicly debated.

In 2001 the WHO published its paper "*Guidance on Xenogeneic Infection/Disease Surveillance and Response: A Strategy for International Cooperation and Coordination"* (WHO 2001b) to promote an international xenogeneic infection/disease event surveillance network. This report also stresses a further discussion of ethical issues: the need to protect patients on the one hand and the need to protect the public health on the other hand.

In 2003 the WHO Executive Board agreed that the Director-General should establish an expert group to prepare a report addressing how the WHO should proceed in dealing with xenotransplantation, for the Board's consideration in January 2004. In October 2003, 37 clinicians, ethicists, social scientists and government officials met in Madrid to discuss "issues of global concern in ethics, access and safety in tissue and organ transplantation" (WHO 2003). In the resulting report xenotransplantation is described as a "potential opportunity" to overcome organ shortage, but clinical trials should be strictly regulated (WHO 2004). The role of the WHO could be to encourage nations to find consensus on basic principles in xenotransplantation regulation. Based on these discussions the Secretariat wrote its report "Human organ and tissue transplantation" (WHO 2003) and presented a draft resolution which addresses allogenic transplantation and xenotransplantation. The recommendations were adopted in the 57th World Health Assembly (WHA57.18). It urges member states to allow xenotransplantation only when effective national surveillance mechanisms are in place and to cooperate in the formulation of international recommendations and guidelines. It requests the Director-General to facilitate communication and international collaboration, to collect data and provide information on xenotransplantation activities and to report to the Health Assembly on the implementation of the resolution.

In April 2005 an informal advisory consultation on xenotransplantation resulted in a statement which reminds Member States to implement Resolution WHA57.18.

A global consultation on xenotransplantation clinical trials took place in China, November 2008. It was organized by WHO, in collaboration with the Chinese Ministry of Health, the Central South University of China and the International Xenotransplantation Association (IXA). The consultation resulted in the Changsha Communiqué (WHO 2008). Most of the participants were members of the International Xenotransplantation Association (IXA). Five representatives of WHO participated as well as members of regulatory authorities of different

countries, transplant physicians and surgeons, ethicists and representatives of organ donation organizations (Cooper 2009: 58).

The starting point of this consultation was the assumption that clinical trials take place without national regulatory authority oversight. The Changsha Communiqué lists principles in xenotransplantation and recommendations for the WHO, its member states and investigators and proposers of clinical trials using xenotransplantation products. This report should update and complete WHO guidance for clinical trials. The consultation was perceived as "the WHO's recognition of the immense clinical potential of xenotransplantation" amongst xenotransplantation researchers (Cooper 2009: 60).

The WHO has a global knowledge base on transplantation, and one part of this is an Inventory of Human Xenotransplantation Practices[19]. The University Hospital Geneva and the International Xenotransplantation Association in collaboration with the World Health Organization are working for this inventory to determine the scope of human xenotransplantation practices.

5.1.15.3 Public consultation – and overview/summary of socio-cultural dimension

The consultation process was impermeable. There has been no public consultation.

5.1.15.4 Chart

WHO	**1990 - 2000**	**2006-present**
Principle regulatory Authority	World Health Assembly	
Principal policy	Should only be permitted when effective national surveillance mechanisms are in place; urges international surveillance mechanisms	
Public consultations	None	
Dominant consultative features	Impermeable	
Key cultural features		

[19] http://www.humanxenotransplant.org

5.1.16 References

Akveld, J.E.M.; van Maurik, J.T.A. (2008): Xenotransplantation: The Dutch situation. In: Jansen, Brigitte E.S.; Simon, Jürgen, W. (Ed.): Xenotransplantation. Ethical, Legal, Social and Scientific Background. München, 119-171.

Beckmann, J.P.; Brem, G. Eigler, F. W. et al. (2000): Xenotransplantation von Zellen, Geweben und Organen, Springer, Wissenschaftsethik und Technikfolgenbeurteilung, Berlin, Heidelberg, New York.

Biegelbauer, P., Grießler, E.(2009) "Politische Praktiken von MinisterialbeamtInnen im österreichischen Gesetzgebungsprozess", in: Österreichische Zeitschrift für Politikwissenschaft, 2009/1; pp. 61-78.

Birmingham, Karten (1999): WHO hosts Web discussion on xenotransplantation policy. In: Nature Medicin, 1999, Vol. 5, No. 6, 595.

Bosch, Xavier (1999): Spanish researchers reject xeno moratorium. Nature Medicine, Volume 5, Number 4, April 1999, 361.

Braunegger-Kallinger, Gudrun, Forster, Rudolf, Krajic, Karl, Nowak, Peter (2006): Health Consumer Groups and Policy Making in Europe. Case Study Austria, European Science Foundation, Exploratory Workshop, Vienna, 16.-18. February 2006, unpublished paper.

Burke, Kevin; O'Hara, Seamus; Keon, Niamh; Reid, Colm: European Biotechnology Innovation Systems (EBIS). National Case Study of Ireland. Final Draft Report. http://www.sussex.ac.uk/spru/documents/ireland.pdf, Accessed: 3. August 2009.

Butler, Declan (1999): Europe is urged to hold back on xenotransplants clinical trials. Nature Vol. 397, 28 January 1999, 281-282.

Caloghirou, Yiannis (2000): European Biotechnology Innovation Systems (EBIS). Final Report. The Case Study of Greece. http://www.sussex.ac.uk/spru/documents/ebis_greece_2000-p2js.pdf, Accessed: 03.08.2009.

Canellopoulou-Bottis, Maria (2000): A new law on organ donation in Greece: one more effort to advanced transplants. In: European Journal of Health Law, Vol. 7, 427-439.

CBOS – Centrum Badania Opinii Społecznej (2007): „Opinie o przeszczepianiu narządów", Abruf: 11.8.2009.

CDBI/CDSP-XENO (2000): State of the art report on xenotransplantation. Strasbourg, Working Party on Xenotransplantation under the joint responsibility of the Steering Committee on Bioethics and the European Health Committee of the Council of Europe, July 2000 (http://www.coe.fr/dase/en/qoflife/publi/artreport/tableart.htm).

Committee for Medicinal Products for Human Use (CHMP) 2009: Guideline on xenogeneic cell-based medicinal products. Draft version. http://www.ema.europa.eu/pdfs/human/cpwp/8350809en.pdf, accessed 4.5.2010.

Committee for Proprietary Medicinal Products (CPMP) 2003: Points to consider on xenogeneic cell therapy medicinal product, http://www.ema.europa.eu/pdfs/human/cpwp/119902en.pdf, accessed 4.5.2010.

Cooper, David K. (2009): Global Consultation on Regulatory Requirements for Xenotransplantation in Clinical Trials. Invited Commentary. Xenotransplantation, 2009. Vol. 16, 58-60.

Council of Europe (1997a): Recommendation No. R(97)15 on xenotransplantation. http://www.coe.int/t/dg3/healthbioethic/texts_and_documents/Rec(97)15E.pdf (27.4.2010)

Council of Europe (1997b): Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Oviedo, 4. IV.1997.

Council of Europe (1998): Xenotransplantation. Report Committee on Science and Technology. Doc. 8166. http://assembly.coe.int/documents/workingdocs/doc98/edoc8166.htm (27.4.2010)

Council of Europe (1999): Recommendation 1399(1999)1. Xenotransplantation. Adopted by the Assembly on 29 January 1999 (8th Sitting), http://assembly.coe.int/Documents/AdoptedText/ta99/erec1399.htm (27.4.2010).

Council of Europe (2000): Report on State of the Art. Working Party on Xenotransplantation. CDB/CDSP-XENO (2000) 12, Strasbourg, 7 July 2000, cdbi/dbi-cdsp-xeno/doc), Strasbourg.

Council of Europe (2000): Without title. CDBI/CDBSP-XENO (2000) 12

Council of Europe (2003a): Report on the State of the Art in the field of Xenotransplantation. Working Party on Xenotransplantation. Strasbourg, 21 February 2003, [cdbi/cdbi-cdsp-xeno/doc/divers/XENO(2003)1Estate fo art final], Strasbourg.

Council of Europe (2003b): Recommendation Rec (2003)10 of the Committee of Ministers to member states on xenotransplantation. Adopted by the Committee of Ministers on 19 June 2003 at the 844th meeting of the Ministers' Deputies.

Council of Europe (2003c): Explanatory Report to Recommendation Rec (2003)10 of the Committee of Ministers to member states on Xenotransplantation. Steering Committee on Bioethics (CDBI), European Health Committee (CDSP), CDBI/INF (2003)12, Strasbourg, 19. June, 2003.

Council of Europe (2010a): http://www.coe.int/aboutCoe/index.asp?page=47pays1europe (26.4.2010).

Council of Europe (2010b): http://www.coe.int/aboutCoe/index.asp?page=nosObjectifs&l=en (26.4.2010).

Council of Europe, Committee of Ministers (1999): Reply from the Committee of Ministers to Recommendation 1399 (1999), Xenotransplantation. Doc. 8393, 25. März 1999. http://stars.coe.fr/doc/doc99/edoc8363.htm.

Council of Europe, Parliamentary Assembly (1999): Xenotransplantation. Recommendation 1399 (1999) (1). Provisional edition January 1999.

Cozzi, Emanuele; Tallacchini, Mariachiara; Flanagan, Enda B.; Poerson, Richard N. III; Sykes, Megan; Vanderpool, Harold Y. 2009: The International Xenotransplantation Association consensus statement on conditions for undertaking clinical trials of porcine islet products in type 1 diabetes – Chapter 1: Key ethical requirements and progress toward the definition of an international regulatory framework. In: Xenotransplantation, 16 (4): 203-214.

De Sola, Carlos (1998): Current Developments on Xenotransplantation in the Council of Europe. Annals of the New York Academy of Sciences, Volume 862 Issue Xenotransplantation: Scientific Frontiers and Public Policy, 211-213.

Debré, Patrice (2000): La xénogreffe est-elle une chimère? Médecine Thérapeutique, Vol. 6, No. 6, 450-455. http://www.john-libbey-eurotext.fr/en/revues/medecine/met/sommaire.phtml?cle_parution=175&type=text.html, Accessed 03.08.2009.

Die Bundesversammlung (1996): Xenotransplantation in der Schweiz. Interpellation. Eingereicht von Felten Margith. 5.6.1996. http://www.parlament.ch/D/Suche/Seiten/geschaefte.aspx?gesch_id=19963233, Accessed: 13.8.09

Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:106:0001:0038:EN:PDF, accessed: 04.05.2010.

Directive 2001/20/EC of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, http://www.eortc.be/Services/Doc/clinical-EU-directive-04-April-01.pdf, accessed 4.5.2010.

Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use, http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-1/dir_2001_83/dir_2001_83_en.pdf, accessed 4.5.2010.

Directive 2003/63/EC amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use, http://www.ema.europa.eu/pdfs/human/pmf/2003-63-EC.pdf, accessed 4.5.2010.

Directive 2005/28/EC laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:091:0013:0019:en:PDF, accessed 4.5.2010.

Duda, Juliusz (2007): „Transplantacja ksenogeniczna; wybrane zagadnienia prawne“, http://www.nil.org.pl/xml/oil/oil56/gazeta/numery/n2007/n200704/n20070408, Accessed: 11.8.2009.

Durant, J., Bauer, M. W., Gaskell, G. (Eds.) (1998): Biotechnology in the Public Sphere. A European Sourcebook. Appendix 1. Eurobarometer standard 46.1. Technical Specification. Science Museum, London.

Eidgenössisches Departement des Inneren (2001): Bundesrat setzt Regelung zur Xenotransplantation in Kraft. 23.5.2001. www.admin.ch/cp/d/3b0b56cf_1@fwsrvg.bfi.admin.ch.html download: 13.8.09

Eidgenössisches Departement für Inneres (2007): Faktenblatt Xenotransplantation. Bern, April 2007. www.bag.admin.ch/transplantation/00698/02592/index.html?lang=de, Accessed: 13.8.09.

Enzing, C.; Kern. S. (2002): The Dutch Biotechnology Innovation System: An inventory and assessment of major developments since 1994. www.sussex.ac.uk/spru/documents/netherlandscountryreport.pdf, Accessed: 7.8.2009.

European Commission (2001): Survey on opinions from national ethics committees or similar bodies, public debates and national legislation in relation to Xenotransplantation. Quality of Life Programme.

Fikus, Magdalena (1998): „Nowe oblicze biotechnologii“, http://archiwum.wiz.pl/1999/ 99043900. asp, Accessed: 8.8.2009.

French National Ethics Committee (1999): Opinion on Ethics and xenotransplantation. No. 61. http://www.ccne-ethique.fr/docs/en/avis061.pdf, Accessed 03.08.2009.

Fryś, Aleksandra (2008): Geneza i rozwój bioetyki oraz jej wpływ na kodeksy etyki lekarskiej i pielęgniarskiej w Polsce. Dissertation, Universytet Medyczny Poznań, http://www.wbc. poznan.pl/dlibra/plain-content?id=107877, Accessed: 9.8.2009.

Galloux, Jean-Christophe; Gaumont-Prat, Hélène; Krumscheid, Olaf (2008): Xenotransplantation: Juridical aspects: France. In: Chadwick, R.; Calloux, J.-Ch.; Simon, J.W.; Paslack, R.; Weisenfeld, U. (Ed.): Xenotransplantation. Ethical, Legal, Economic, Social, Cultural and Background, Vol.2. München: AVM. 139-193.

Gesellschaft für Virologie e. V.; Verfasser: Denner, J. (2002): Fortschritte und Risiken bei der Xenotransplantation. Stellungnahme der GfV in Bezug auf Chancen und Risiken der Xenotransplantation. http://www.g-f-v.org/index_de.php4?modul=NEWS& aktion=TEXT&id=13.

Griessler, E. (2008): The Xenotransplantation “Deb ate” in Austria. In: Jansen, Brigitte E.S.; Simon, Jürgen W. (Eds.): Xenotransplantation. Ethical, Legal, Economic, Social, Cultrual and Scientific Background. 147-164.

Griessler, E. (2010): „Weil das so ein heißes Thema ist, rühren wir das besser nicht an.“ Zur Regulierung kontroverser biomedizinischer Forschung in Österreich. In Biegelbauer, Peter (Hrsg.): Governance des österreichischen Innovationssystems, Studienverlag, Innsbruck (forthcoming).

Griessler, E., Bogner, E. (2003): National Report Baseline Evaluation – Austria, Increasing Public Involvement in Debates on Ethical Questions of Xenotransplantation, www.ihs.ac.at/departments/soc/xeno-pta/dt/ergebnisse.html, Accessed: 1.10.2009.

Haniel, A., Rendtorff, T., Winnacker, E.-L. (1999): Zur ethischen Beurteilung der Xenotransplantation. Stellungnahmen des Instituts für Technik-Theologie-Naturwissenschaften (TTN) an der LMU München. http://www.ttn-institut.de/download/xeno.zip.

Haniel, Anja (Hrsg., 2002): Tierorgane für den Menschen? Dokumentation eines Bürgerforums zur Xenotransplantation, Herbert Utz Verlag.

Hanisch, Ernst (2005): Der Lange Schatten des Staates. Österreichische Gesellschaftsgeschichte im 20. Jahrhundert, in: Herwig Wolfrag (Ed.), Österreichsche Geschichte 1890–1990, Wien.

Härtel, Ingo (2003): The Fate of The Council of Europe's Recommendation on Xenotransplantation. Annals of Transplantation,Vol. 8, No. 3, 53-55.

Hüsing, B. (2004a): Increasing Public Involvement in Debates on Ethical Questions of Xenotransplantation. Monitoring of International Developments in Xenotransplantation. Karlsruhe.

Hüsing, B. (2004b): Update Report: Baseline evaluation of the scientific state of the art in XTP of Organs. Increasing Public Involvement in Debates on Ethical Questions of Xenotransplantation. Studie im Auftrag der Europäischen Kommission, Fraunhofer Institut for Systems and Innovation Research, Karlsruhe, http://www.ihs.ac.at/departments/soc/xeno-pta/results_1.html, Accessed: 7.9.2009.

Hüsing, B., Zimmer, R. (2003): Increasing Public Involvement in Debates on Ethical Questions of Xenotransplantation. National Report Baseline Evaluation: Germany. www.ihs.ac.at/departments/soc/xeno-pta/dt/ergebnisse.html, Accessed: 1.10.2009.

Hüsing, B.; Engels, E.-M.; Frick, T. et al. (1998): Technologiefolgen-Abschätzung Xenotransplantation. Bern: Schweizerischer Wissenschaftsrat, 246 p.

Hüsing, B.; Engels, E.-M.; Gaisser, S. et al. (2001): Zelluläre Xenotransplantation. Bern: Zentrum für Technologiefolgen-Abschätzung beim Schweizerischen Wissenschafts- und Technologierat, 331 p.

Julvez, Jean; Tuppin, Philippe; Cohen, Sophie (1999): Survey in France of response to xenotransplantation. The Lancet, Vol. 353, February, 726.

Kandic-Popovic, Zorica (1998): „The Legal Protection of Fundamental Human Values in Central and Eastern Europe and Modern Biotechnology: Towards European Harmonization", http://rss.archives.ceu.hu/archive/00001061/, Accessed: 11.8.2009.

Kirchenamt der Evangelischen Kirche in Deutschland; Sekretariat der Deutschen Bischofskonferenz (Ed.) (1998): Xenotransplantation – eine Hilfe zur ethsichen Urteilsxbildung. Vorbereitet von einer Arbeitsgruppe im Auftrag des Kirchenamts der Evangelischen Kirche in Deutschland und des Sekretariats der Deutschen Bischofskonferenz. Gemeinsame Texte. Vol. 13, Bonn, Hannover.

Kriari-Catranis, Ismini (2008): Xenotransplantation: Legal and Ethical Aspects in Greece. In: Jansen, B.E.S.; Simon, J.W. (Ed.), Xenotransplantation. Ethical, legal, economic, social, cultural and scientific background. Volume 1. Saarbrücken: VDM. 164-190.

Kuta, Wojcieck (2009): „Choroba skazana na medialny sukces“, http://finanse.wp.pl/kat, 58514,title,Choroba-skazana-na-medialny-sukces,wid,11343911,wiadomosc.html?ticaid =188bb, Accessed: 9.8.2009.

Macheiner, Margret (2005): Die Durchsetzung von Patienteninteressen und Ärzteinteressen in Österreich. Ein Spannungsfeld zwischen „Konsumenten und Produzenten“. Unveröffentlichtes Manuskript, Salzburg.

McLean, Sheila; Williamson, Laura (2005): Xenotransplantation: law and ethics. Aldershot: Ashgate Publishing.

Meller, J. (2001): „Etyczna problematyka przeszczepiania narządów“, http://www.cecib. uksw.edu.pl/index.php?option=com_content&task=view&id=103&Itemid=42&limit=1 &limitstart=4, Accessed: 9.8.2009.

Melo, Helena; Brandao, Cristina, Rego, Guilhermina, Nunces, Rui (2001): Ethical and legal issues in Xenotransplantation. Bioethics, Volum 15, Number 5/6 2001, 427-442.

Ministerstwo Nauki i Szkolnictwa Wyższego (Ed.) (2007) [Ministerium für Wissenschaft und Hochschulwesen]: Stan i kierunki rozwoju biogospodarki [Stand und Bereiche der Entwicklung in den Biotechnologien], http://old.biotechnologia.com.pl/biotechnologia/ 12/928, Accessed: 9.8.2009.

National Health & Medical Research Council (2002): Draft guidelines and discussion paper on xenotransplantation, http://www.nhmrc.gov.au/about/committees/expert/gtrap/_files/ xeno.pdf, Accessed: 7.8.2009.

Neue Zürcher Zeitung (1998): Xenotransplantation – Ringen um Regulierung. Europa- oder gar weltweites Moratorium angestrebt. http://xenotransplant.ineu.org/xenotrans/articles/Xenotrans_NZZ_7.8.98_RTF.htm (26.4.2010).

Neue Zürcher Zeitung (1998): Xenotransplantion. Europa- oder gar weltweites Moratorium angestrebt. 7.8.1998. http://xenotransplant.ineu.org/xenotrans/articles/Xenotrans_NZZ_7.8.98_RTF.html, Accessed: 13.8.09.

Nys, Herman; Trouchet, Caroline (2008): Xenotransplantation: Ethical, Social, Economical and Legal Aspects: Belgium. In: Chadwick, R.; Calloux, J.-Ch.; Simon, J.W.; Paslack, R.; Weisenfeld, U., Xenotransplantation. Ethical, Legal, Economic, Social, Cultural and Background, Vol.2. München: AVM. 97-137.

OECD (1996): Advances in Transplantation Biotechnology and Animal to Human Organ Transplants (Xenotransplantation). Paris

OECD (1999): Main Science and Technology Indicators, Paris.

OECD (1999b): Xenotransplantation. International Policy Issues. OECD Proceedings. Paris

OECD (2009): Regulatory Development in Xenotransplantation in Switzerland . www.oecd.org/document/44/0,3343,en_2649_34537_2348908_1_1_1_1,00.html, Accessed: 13.8.09

OECD Health Data 1998, Paris.

OECD/WHO (2001): OECD/WHO Consultation on Xenotransplantation Surveillance. Summary. Held in Paris on 4-6 October 2000. Document No. DSTI/STP/BIO(2001)11/FINAL. Paris: OECD (http://www.olis.oecd.org/olis/2001doc.nsf/43bb6130e5e86e5fc12569fa005d004c/7d4e7b2820d508dfc1256af1005328fc/$FILE/JT00115450.PDF).

OECD: Regulatory Developments in Xenotransplantation in France. http://www.oecd.org/document/29/0,3343,en_2649_34537_1887773_1_1_1_1,00.html, Accessed 03.08.2009.

Organizatión National des Tralsnplantes (1999): International Data on Organ donation and Transplantation in 1998, www.msc.es/on/ing/data/europe.htm. Downloaded on 09.11.1999.

Paslack, Rainer (2008): Xenotransplantation: A comparative analysis on the basis of national and international studies and reports. In: Jansen, Brigitte E. S; Simon, Jürgen, W. (Eds.): Xenotranplantation. Ethical, Legal, Economic, Social, Cultural and Scientific Background, Vol. 1, pp. 79-145, VDM, Saarbrücken.

Pereira de Melo, Helena (2008): Xenotransplantation: Portugal. In: Jansen, B.E.S.; Simon, J.W. (Ed.), Xenotransplantation. Ethical, legal, economic, social, cultural and scientific background. Volume 4. München: Martin Meidenbauer Verlagsbuchhandlung.

Plattner, Gian-Reto (1999a): Europäisches Moratorium für Xenotransplantation. http://xenotransplant.ineu.org/xenotrans/people/Plattnergr/Xenotranspl._SM__RTF_Kopietxt.htm (24.4.2007).

Plattner, Gian-Reto (1999b): Xenotransplantation. In: Council of Europe (Ed.): International Conference of the Council of Europe on Ethical Issues Arising from The Application of Biotechnology. Proceedings. Oviedo (Spain), 16-19 May 1999, Council of Europe Publishing, 33-34.

Polskie Zrzeszenie Inzynierów i Techników Sanitarnych (Ed.) (2007): Poradnik Genetycznie Modyfikowane Organizmy. Poznań.

Przestalski, Andrzej/Suchocki, Bolesław/Twardowski, Tomasz (1998): „Poland“, in: Durant, John/ Bauer, Martin W./Gaskell, George (Hg.): Biotechnology in the Public Sphere. London: Science Museum, S. 118–129.

Recommendation No R(97)15 of the Committee of Ministers to member states on xenotransplantation (adopted by the Committee of Ministers on 30 September 1997, at the 602nd meeting of the Ministers' Deputies); http://www.coe.int/T/E/Social%5FCohesion/Health/Recommendations/Rec(1997)15.asp#TopOfPage, Accessed April 23, 2004.

Recommendation Rec(2003)10 of the Committee of Ministers to member states on xenotransplantation (Adopted by the Committee of Ministers on 19 June 2003 at the 844th meeting of the Ministers' Deputies); https://wcd.coe.int/ViewDoc.jsp?id=45827, Accessed 1.10.2009.

Regulation 1394/07 of the European Parliament and of the Council on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:324:0121:0137:en:PDF, accessed 4.5.2010.

Reiss, T. (1999): National Report Austria. In: European Commission: Inventory and analysis of biotech programmes and related activities in all countries participating in the Biotechnology Programme 1994-1998, Luxembourg.

Rowiński, Wojciech (2002): „Aspekty prawne i etyczne przeszczepiania narządów“, http://www.przeszczep.pl/print/do_druku_pl.php?id_102, Accessed: 10.8.2009.

Rowiński, Wojciech et al. (2003): „Problemy etyczno-obyczajowe przeszczepienia narządów“, http://www.przeszczep.pl/print/do_druku_pl.php?id_104, Accessed: 10.8.2009.

SAMS (2001): Medical-Ethical Principles on Xenotransplantation. Statement of Position of the SAMS. Swiss Medical Weekly 200 1; 131: 388–394, www.smw.ch/docs/pdf200x/2001/25/smw-09735.pdf, Accessed: 13.8.09.

Schlitt, H.; Brunkhorst, R.; Haverich, A. et al. (1999): Attitude of patients toward transplantation of xenogeneic organs. Langenbeck's Archives of Surgery/ Deutsche Gesellschaft für Chirurgie 384, Nr. 4, 384-385.

SCMPMD 2001: Opinion on the State of the Art Concerning Xenotransplantation. Adopted by The Scientific Committee on Medicinal Products and Medical Devices on 1st October 2001.

Seebach, Jürgen: Geregelte Xenotransplantation. Übertragung von Tierorganen nach wie vor unrealistisch. In: Neue Zürcher Zeitung, 28.6.2001, p. 17.

Simon, Jürgen W. (2008): Xenotransplantation: An international overview. In: Jansen, Brigitte E. S; Simon, Jürgen, W. (Eds.): Xenotransplantation. Ethical, Legal, Economic, Social, Cultural and Scientific Background, Vol. 2, pp. 39-52, AVM, München.

Smorag, Zdźisław et al. (2008): „Animal reproduction biotechnology in Poland“, in: International Journal of Developmental Biology, Nr. 52, S. 151–155.

Sommerauer, Andrea (2008): Transplantationen. Lebendspender dringend gesucht. Der Kurier, 6.6.2008, 19.

Sprawozdanie (1995): „Sprawozdanie z 53 posiedzenia Senatu w dniu 14 września 1995“, S. 2–30, http://www.senat.gov.pl/k3/dok/sten/053/53spr1.pdf, Accessed: 10.8.2009.

Straßburger, J. 2008: The regulation of xenotransplantation in Germany and in the European Union. In: Xenotransplantation, 15 (5): 299-300.

Tallacchini, Mariachiara; Beloucif, Sadek 2009: Regulatory issues in xenotransplantation: recent developments. In: Xenotransplantation, 14(2): 180-185.

The Dutch Consumer and Biotechnology Foundation (2001): Xenotransplantation. Is and Should it be Possible? Final Report in respect of the public debate on xenotransplantation. The Hague,

Twardowski, Tomasz/Michalska, Anna (2001): „Kontrowersje – Klonowanie“, in: Medycyna Wieku Rozwojowego, Vol. 5, Nr. 1, S. 181–194.

Van Rongen, Eric (1998): Xenotransplantation: Perspectives fort he Netherlands. In: Xenotransplantation: scientific frontiers and public policy, Annals of the New York Academy of Science, Dec. 30, vol. 862, 1998, p. 177-183.

Vier Pfoten, Position der ”Vier Pfoten” Xenotransplantation (3.12.1999).

Virusepidemiologische Informationen 1998/3.

Węgrzynowicz, Remigiusz (2000): „Ochrona zwierząt poddawanych doświadczeniom w świetle prawa i norm etycznych“, http://www.ekoimy.most.org.pl/02_01_09_2000_ artykul.htm, Accessed: 7.8.2009.

WHO (1997): Report of WHO Consultation on Xenotransplantation. World Health Organization, Geneva, Switzerland, 28-30 October 1997 (http://www.who.int/emc-documents/zoonoses/ docs/whoemczoo982.pdf).

WHO (1998a): Report of WHO Consultation on Xenotransplantation. World Health Organization, Geneva, Switzerland, 28-30 October 1997 (http://www.who.int/emc-documents/zoonoses/ docs/whoemczoo982.pdf).

WHO (1998b): Xenotransplantation: Guidance on Infectious Disease Prevention and Management. WHO/EMC/ZOO/98.1. World Health Organization: Geneva, Switzerland (http://www.who.int/emc-documents/zoonoses/docs/whoemczoo981.pdf).

WHO (2001b): WHO Guidance on Xenogeneic Infection/Disease Surveillance and Response: A Strategy for International Cooperation and Coordination (WHO/CDS/CSR/EPH/2001.2) (http://www.who.int/emc-documents/zoonoses/docs/whocdscsreph20012.pdf).

WHO (2003): Human Organ and Tissue Transplantation. EB113/14.

WHO (2004): Ethics, access and safety in tissue and organ transplantation: Issues of global concern. Report. WHO.

WHO Guidance on Xenogeneic Infection/Disease Surveillance and Response: A Strategy for International Cooperation and Coordination (WHO/CDS/CSR/EPH/2001.2) (http://www.who.int/emc-documents/zoonoses/docs/whocdscsreph20012.pdf).

WHO/OECD (2001): OECD/WHO Consultation on Xenotransplantation Surveillance: Summary (WHO/CDS/CSR/EPH/2001.1) (http://www.who.int/emcdocuments/zoonoses/docs/whocdscsreph20011.pdf).

Wijnberg, Bart; Houssin, Didier (2001): Xenotransplantation and the Council of Europe. Xenotransplantation 2001: 8: 85-86.

Wissenschaftlicher Beirat der Bundesärztekammer (1999): Stellungnahme des Wissenschaftlichen Beirates der Bundesärztekammer zur Xenotransplantation. In: Deutsches Ärzteblatt 96, Nr. 28, A12930-A1926.

World Health Assembly 2004: 57th World Health Assembly. WHA57.18.

www.xenome.eu/legal_framework_xenotransplantation.aspx?fr=belgium#salto

Zentrum für Technikfolgenabschätzung, Bundesamt für Gesundheit, Schweizerischer Nationalfonds zur Förderung wissenschaftlicher Forschung (2001): Transplantationsmedizin. 24.-27.November 2000 in Bern. Bericht des Bürgerpanels, TA-P2/2000d. www.ta-swiss.ch/d/arch_biot_tran.html download: 13.8.09.

5.2 Italy and The Holy See

Agnes Allansdottir

5.2.1 Introduction and Methods

Over the last two decades Italian political life has been undergoing profound changes. The corruption trials of the early nineties basically brought down the post WW II political party structure, most importantly the Christian Democrats. What followed has been described as the attempt of political parties and associations to capture the elusive Catholic vote. Some analysts see this as one of the main reasons for the obstacles to regulatory activities with regards to ethically sensitive issues.

In contrast to some other European countries Italy does not seem to aim to become an international leader in the development of science and development as the future of scientific research has not been high on the political agenda in recent years. A notable exception however is biomedical research for the benefit of human health and wellbeing, a sector that has grown considerably in recent years.

The Italian public debate over xenotransplantation is intimately linked with the much more prominent debate over human embryonic stem cell research as, by the end of the millennium, those two strands of research were both proposed as viable solutions to the growing social problem of the shortage of human organs for transplantation.

The synopsis presented in the following pages is based on the author's previous research in this area[1] and a preliminary reading of the documents published by the major stakeholders in the debate over xenotransplantation. It also provides an overview of developments in approaches to public consultation and public participation exercises in Italy over the last decade.

5.2.2 Overview of landmark developments and timeline – Key features of policy-making and process

Italian debates over the life sciences were catalysed by the news of Dolly the cloned sheep in early 1997. The news arrived in the midst of a policy scene already in turmoil over the juridical status of the human embryo.[2] At the time there was no national legislation in place

[1] BEP: Biotechnology and the European Public (BIO4-CT95-0043); EUDEB: European Debates on Biotechnology: Dimensions of Public Concerns (BIO4-98-0488); LSES: Life Sciences in European Societies (QLRT/1999/00286)

[2] The issue centres on the moment when human life begins, at the moment of conception, and the subsequent ramifications for the juridical status of the human embryo as already as a person at that moment or not. In the summer of 1996 The National Bioethics Committee published a document advocating the former that was met the establishment of the Manifesto per la Bioetica Laica (Manifesto for Secular Bioethics). These are still the basic fault lines in Italian bioethics and policy discussions, between the principle of the sanctity of human life and the principle

on reproductive technologies, prompting the then Minister of Health to use an "emergency" instrument to ban cloning by ministerial decree valid for 90 days at a time.[3] The news of the clone also had the effect of directing policy makers into a more proactive approach trying to foresee future developments and have regulations in place at earlier stages of technology development.

Xenotransplantation was already a growing and a promising field of publicly funded research at the time, so attention quickly turned towards its prospects as well as potential associated risks. In late 1997, when the *Council of Europe* called for a moratorium on xenotransplantation, the Italian regulatory wheels were set in motion.

The years of 1998 and 1999 saw a growing unease over biotechnology developments in Italy, and diverse issues such as intellectual property rights (patents on life), transgenic animals and plants, cloning and GM were often fused in public discourse. At the same time, the discourses on cloning became more refined and distinctions were made between reproductive and therapeutic cloning. The former was condemned, while the latter became the object of heated socio cultural debate for years to come.

In January 1999 *The Parliamentary Assembly of the Council of Europe* declared itself in favour of a moratorium on the clinical applications of xenotransplantation and asked the Committee of Ministers to initiate a study relating to the different aspects of the relevant issues.[4]

The *National Bioethics Committee*[5] deliberated swiftly on this issue and adhered to the call for a moratorium on clinical trials in November 1999. The decision was based on an ethical criterion of precaution while encouraging incentives for scientific research in this area. Further, the CNB explicitly encouraged initiatives to promote and stimulate a public debate to achieve social consensus surrounding xenotransplantation, but so far that has remained a pledge on paper only.[6]

In April the previous spring the first national law on organ donation was passed in Italy.[7] Initially citizens could choose to become organ donors by applying for donor cards to the relevant health authorities but that was changed into presumed consent the following year on

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of the quality of human life. Note that the debate is based on the notion of the dignity of Human life within a worldview that essentially considers animals at the service of humankind.

[3] Initially the decree banned all forms of cloning, both animal and human but as time went by the ban on animal cloning was lifted, perhaps also after the Carabinieri confiscated a cloned bull or a calf aptly named Galileo.

[4] Recommendation 1399 (1999)

[5] The National Bioethics Committee was established by a decree signed by the President of the Council of Ministers on 28 March 1990 as a consultation body that reports directly to the Council of Ministers. http://www.governo.it/bioetica/eng/index.html

[6] http://www.governo.it/bioetica/pdf/37.pdf

[7] Law 91/1999, included the establishment of National Institute for Transplantations, and explicitly bans any form of organ commerce, including the import of organs from countries where the sale of organs is allowed. In Italy as in most countries strongly inspired by a Catholic cultural matrix, the societal value placed on acts of donation and charity is historically high.

technical grounds. This regulation is widely regarded as being successful with organ donation very quickly becoming a matter of accepted social practice.

The following year the other main governmental advisory body (the *National Committee for Biosafety Biotechnology and Life Sciences*) published the guidelines for clinical trials in xenotransplantation.[8]

The prospects of therapeutic cloning and the whole issue of human embryonic stem cell research somewhat shifted the framing of the debate over xenotransplantation as both approaches were essentially proposed as new, radical, but promising solutions to a common societal problem, that of organ shortage.

Institutions of the *Holy See*[9] have long played a central role in shaping the path of developments in biomedical science and research in the life sciences. *The Pontificial Academy for Life*[10] organised a series of meetings between representatives of science and faith to discuss the future of xenotranplantation worldwide. These meetings resulted in a document on *Xenotransplants: Scientific Aspects and Ethical Considerations,* published in September 2001. The document concludes:

> "Xenotransplants can be considered a great scientific challenge, a realistic therapeutic option and a project in line with ethical guidelines as long as the rights of individuals and communities to safeguard health are protected and equal access to the therapy is ensured."[11]

After those rather eventful four years with a flurry of regulatory activity, little has happened in Italy in this regard. That said, research continues to progress and, in line with the guidelines published by the CNBB in 2000, at least six centers have been authorised to conduct further research on xenografting. However, this has not so far become a subject of public debate. This might partly be because the issue is perceived as being already settled but is surely also due to the debate about human embryonic stem cell research dominating the socio political debate over the regulation of the life sciences. Apart from considerations of a more ethical nature, that are primarily to be decided on a national level, the focus of regulatory

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[8] The National Committee for Biosafety, Biotechnology and Life Sciences was set up in 1992 in order to oversee the implementation of the two EC directives of genetically modified organisms. The CNBB has a clear mandate in terms of a scientific expert-led approach to risk while the CNB's mandate covers the ethical and moral issues surrounding biomedicine and life sciences http://www.governo.it/biotecnologie/documenti.html

[9] www.vatican.va

[10] The Pontificial Academy for Life was established in 1994 by John Paul II's Moto Proprio "*Vita Mysterium"* The Academy has a prevalently scientific character directed towards the promotion and defence of human life. The mandate is to study questions and issues pertaining to human life, to foster a culture of life and inform the Church, biomedical institutions, health care institutions and association, mass media and civil community in general about its study and research activities. http://www.academiavita.org/portal.jsp?lang=english

[11] http://www.vatican.va/roman_curia/pontifical_academies/acdlife/documents/rc_pa_acdlife_doc_20010926_xenotrapianti_en.html

activity has shifted again to the European level with the Advanced Therapy Directive of 2007. How that will play out on a national level remains to be seen.

5.2.3 Public consultation – and overview/summary of socio-cultural dimensions

Italy has traditionally been characterised by a primarily technocratic approach to policy making on science and technology where decisions would be taken by civil servants in collaboration with scientific experts in the relevant field, and discussed in parliamentary committees before being put before Parliament and Senate. There is no strong tradition of technology assessment and the Italian Parliamentary Technology Assessment body has little room for public dialogue in their deliberations.[12]

On *a national level* there are few provisions for public consultation, with the notable exception of national referenda. Italian law allows this when 500,00 citizens have signed a petition to hold a referendum, in two instances. Firstly, as a constitutional referendum for the approval or disapproval of amendments of constitutional law. Secondly, as a legislative referendum to abrogate an existing law. The latter approach was put to the test in a national referendum in June 2005 on the controversial law on reproductive technologies and human embryo research that came into force in 2004.[13] The referendum failed to reach the required quorum of 50% + 1 of the electorate and therefore the law is still in place. Other instruments for public consultation on a national level are simply not available, with the exception of surveys and other forms of commissioned social research.

The last two decades have seen increased decentralisation with substantial political power handed over *from the state to the regions*.[14] This is, for example, the case in health care as well as the environment and urban development. A constitutional law from 2001[15] introduced the principle of subsidiarity, under which citizens and associations can promote initiatives of "common interest". The Tuscan Region has gone furthest and passed a regional law at the end of 2007 that effectively introduces public participation into decision making processes in the region. This new framework has given rise to a series of initiatives, mostly relating to participating in urban design and development, environmental issues and waste disposal. Some of these initiatives have a strong European dimension to them, such as the recent

[12] http://www.eptanetwork.org/EPTA/members.php?country=Italy, http://vast16.camera.it/ recent activities have mostly regarded Italian participation in EC space programmes.
[13] Law 40/2004 came into force after a legislative void with regards to the regulation of reproductive technologies in Italy. Before that a memo had been issued by the Ministry of Health in 1984 that banned heterologous IVF in public structures while the private sector became known as the Far West of reproduction. The Law 40/2004, bans IVF with biological material from donors, allows the creation of up to 3 embryos and all of them have to be implanted to avoid the problem of left over embryos. It bans pre-implantation genetic screening as well as the use of human embryos for research purposes.
[14] The Italian administrative units are The Italian Republic, Regions, Provinces and Municipalities or cities.
[15] Constitutional Law 3/2001 article 118.

Town Meeting in Florence on climate change and global warming organised in collaboration with several other European cities.[16]

Increasing regionalisation of public health and health care issues has also opened up new possibilities for participation in health issues. Some municipalities and provinces have experimented with PP for health budget decisions and regions such as Tuscany and Piedmont have actively adopted the translational approach to their growing biomedical research complexes.

Italy is a country with long history of a thriving civil society. Participation in the voluntary sector, associations and charities is much higher than in many other European countries. The organisation tends to be somewhat "bottom up" or grass-root driven. These capillary networks all across the country formed the back bone of recent mobilisation over GM food and agriculture promoted by the *Fondazione dei Diritti Genetici* (The Foundation for Genetic Rights) with the stated objective of restoring the role of society in the governance of innovation. [17] Several other actors have become very active in recent years, perhaps most of all *La Cittadinanza Attiva* (Active Citizenship) set up in 1978, which was granted ministerial recognition as a Consumer Organisation in 2000. Its main objective is "the promotion of civic participation and the protection of citizen's rights in Italy and Europe" and it advocates public participation in the policy making process.[18] By now 16 patient groups adhere to this organisation.

In short, the processes of decentralisation have opened up new possibilities and horizons for public participation in Italian policy making. As matters stand today public consultation and participation in policy decision making can be regarded as an *experiment in action* in contemporary Italy. In general the impact of initiatives remains, for the time being, somewhat unclear.

[16] It is tempting to see a political "bias" to those regional and local initiatives as they tend to be more advanced under centre left local government. A further complicating factor is the economic disparity between the Italian regions with the risk of public consultation exercises become a privilege for the more affluent parts of the country.
[17] http://www.fondazionedirittigenetici.org/fondazione/en/
[18] http://www.cittadinanzattiva.it/who-we-are.html

5.3 Spain

Agnes Allansdottir

5.3.1 Introduction and Methods

The Spanish approach to policy making in the life sciences has traditionally been be expert lead and highly technocratic. Spain has undergone rather profound changes in recent decades and although successive governments have underlined the strategic importance of increased funding for science and technology as a key driver in the modernisation of the country investments remain rather low as compared with many other EU countries. The series of Eurobarometer surveys indicate that the Spanish public is receptive of science and technology and particularly so when it comes to biomedical research. Further, Spain does allow the cultivation of genetically modified crops and that can be regarded as openness towards developments in the life sciences.

This short report is almost entirely based on desk research drawing upon published publicly available documents and literarute reviews and is inspired by an earlier report by David Santos and Emilio Munoz on xenotransplantation, policy overview and public dialogue in Spain published in 2003[19].

It is widely reported that Spain has the highest organ donor rate in the world at 34 deceased donors per million inhabitants, partly due to the adoption of a general opt-out system early on.[20] There is a whole history to the so-called Spanish model originating in the 1980ies and instutionalised with the establishment of the *National Transplant Organisation* in 1989.[21] To carry out these tasks, the NTO functions as a technical operative unit, grounded in the principles of cooperation, efficacy, and solidarity, that coordinates the conduct of donation, extraction, preservation, distribution, exchange, and transplantation of organs, tissues and cells throughout the whole Spanish Health Care System. The Spanish health system along with education and other major policy areas is highly and effectively regionalised as set out in the Constitution, dated in 1978, of the Kingdom of Spain where political power is channelled through the central state and the 17 autonomous communities (*Comunidad Autónoma)*. So for our story, transplantations policies are centrally governed and locally managed.[22] This has also translated into a highly efficient and highly skilled institutional network for organ transplantations across the country.

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[19] Santos, D & Munoz, E. (2003) "Increasing Public Involvement in Debates on Ethical Questions of Xenotransplantation" National Report Baseline Evaluation: Spain http://www.ihs.ac.at/departments/soc/xeno-pta/xeno_Spain.pdf

[20] http://www.iaod.org/, see also: http://www.msc.es/gabinetePrensa/notaPrensa/desarrolloNotaPrensa.jsp?id=127

[21] http://www.ont.es/Home/Paginas/default.aspx?id_nodo=124

[22] The Spanish model (NTO) was later adopted by other countries such as France, Italy and more recently Portugal and to some extent exported to Central and South America and is contrasted with the OEO approach or Multinational Organ Exchange Organisation prevalent in most "older" members of the European Communities http://ec.europa.eu/health/ph_threats/human_substance/oc_organs/docs/oc_organs_061_en.pdf

5.3.2 Overview of landmark developments and timeline – Key features of policy-making and process

Spain was a forerunner in preparing the regulatory grounds for eventual xenotransplantations. Already in May 1997 the Permanent Committee on Transplantation of the Interterritorial Council of the Spanish National Health System approved a proposal to form a Subcommittee on Xenotransplantation. In consideration of the broad spectrum of issues raised by xenotransplantation, the Ministry of Health appointed experts from different backgrounds to this Subcommittee"[23] The experts for the most part had a medical science background and initially there did not seem to be much room or scope to enlarge that pool of expertise. Forms of participatory technology assessment and citizens involvement, apart from the social practices already institutionalised within the Spanish approach to organ transplantation, did not seem a priority. However, it was made clear from the outset that patients and their families were to be fully informed about the continuous need for monitoring and the eventual constraints such controls would impact upon their private lives.

The Subcommittee was formed on 29 June 1997, and released a background document on xenotransplantation and the Spanish Guidelines on Xenotransplantation on 17 June 1998.[24]

The Guidelines require that before human trials can begin, preclinical studies must demonstrate six-month survival and function of cells, tissues and organs and absence, during the same time period, of transmission of infectious agents. In case such transmission is detected, the guidelines also require that there be no signs of infections for 12 months. The Guidelines indicate that "the clinical protocol should include a procedure to inform the recipient of his/her responsibility to educate close contacts and offer him/her assistance with this education process, if needed".

Surveillance and archiving procedures are carried out by each clinical centre that is on a local level but under the central oversight of the National Transplantation Organisation and the Subcommittee on xenotransplantation.[25]

The publication by the Subcommission of both a background document on xenotransplantation and The Spanish Guidelines on xenotransplantation prompted claims by Xavier Bosch then head of the Subcommission, published in *Nature Medicine* in August, that

[23] http://www.oecd.org/document/36/0,3343,en_2649_34537_2352420_1_1_1_37437,00.html
http://www.xenome.eu/legal_framework_xenotransplantation.aspx?fr=summaryspain#salto
[24] The document: Subcomsión de xenotrasplante de la Comisión Permanente de Trasplantes del Consejo Interterritorial del Sistema Nacional de Salud, Organización Nacional de Trasplantes, Ministerio de Sanidad y Consumo, 1998, Madrid.
[25] "Xenotrasplante", . Subcomisión de Xenotrasplante de la Comisión Permanente de Trasplantes del Consejo Interterritorial del Sistema Nacional de Salud Organización Nacional de Trasplantes, Ministerio de Sanidad y Consumo, 1998, Madrid

Spain was the first country in the world to issues such guidelines for xenotransplantation, pre-clinical activities and eventual clinical trials.[26]

The issue of xenotransplantation was clearly less controversial in Spain than in international policy circles as after the Council of Europe proposed a moratorium, *Nature Medicine* carried an article explaining how Spain was the only country that immediately *opposed* the proposed moratorium:

"A fight has erupted between the Council of Europe's Parliamentary Assembly and Spanish scientists over a February report by the council calling for a moratorium on clinical trials of xenotransplantation. Leading researchers in Spain — a country with one of the largest organ transplant programs in the world — have announced their opposition to the decision and their determination to press ahead with research in this area.[27]

Further, in the article Rafael Matesanz, the then head of the Permanent Transplantation Commission and the Chair of the Transplants Commission of the European Council is reported as stating that the proposed moratorium was a political and inappropriate decision, disregarding the opinion of technical experts and thus risking putting the US ahead of Europe in this promising field of research.[28]

As in many other Mediterranean countries animal welfare issues have traditionally not been a pressing concern in Spain, consistent with a hierarchical cultural worldview that for the most part puts a high value on the dignity of human life and tends not to question the exploitation of animals for the wellbeing of humans. According to the report by the Council of Europe[29] existing Spanish national regulation on animal welfare issues adequately covers issues surrounding xenografting and xenotransplantation.

By 2003 the interest in xenotransplantation in Spain appeared to be waning, and availability of research funds was declining. Santos and Munez wrote at the time: *"At present, the main research carried out in Spain is searching the overcoming of the graft rejection problems following the hyper-acute phase. Researchers are employing immune suppressors by implanting heart pigs in baboons, using the installations and infrastructure of the Hospital Juan Canalejo, in A Coruña (the northwest coast of Spain)*."[30][31] In their paper they also report on extensive interviews with stakeholders and the vision of xenotransplantation and citizen participation was rather crisp. The "debate" was almost entirely expert lead: *"The*

[26] http://www.nature.com/nm/journal/v4/n8/pdf/nm0898-876b.pdf
[27] http://www.nature.com/nm/journal/v5/n4/pdf/nm0499_361a.pdf
[28] See discussions in Santos & Munoz (2003) note 1.
[29] Council of Europe (2003) Report on the State of the Art in the Field of Xenotransplantation.
[30] *Santos, D & Munoz, E. (2003)* "Increasing Public Involvement in Debates on Ethical Questions of Xenotransplantation" National Report Baseline Evaluation: Spain", page 56 http://www.ihs.ac.at/departments/soc/xeno-pta/xeno_Spain.pdf
[31] This research was directed by Rafael Manez and supported by Novartis using transgenic pigs bought form Immutran. See Persson, A. & Welin, S. (2008) *Contested Technologies: Xenotransplantation and Humane Embryonic Stem Cell Research.* Nordic Academic Press, p. 77

recommendations on how to establish and develop mechanisms to debate the new technologies, and, in particular, the case of xenotransplantations are embodied essentially in the opinion expressed by the experts".

There are some important similarities between the story of xenotransplantation in Spain, Italy and the Holy See, both were strongly framed as ethically acceptable solution to the organ shortage and preferable over the use of human embryonic stem cells as means to obtain a comparable goal[32]. Santos and Munez wrote in their report from 2003: *"Some interviewees pointed out that the ethical aspects should be dealt in the information conveyed to the public on biotechnology as well as the technical questions on the technology are presented. News and information on these ethical aspects of possible technical developments in the clinical practice are missing. The situation is exactly the opposite for the case of stem cells where the ethical implications are being the most frequently discussed and, in opinion of some of the experts, responsible for stopping the research on them".*

The comparisons, contrasts and eventual tensions between promoting xenotransplantation and the eventual use of human embryonic stem cell derived from surplus embryos originally created for reproductive purposes were greatly eased by the passing of the Assisted Reproduction Act (Law 45/2003)[33] that allows research using human embryonic stem cells for research under strict condition and the Royal Decree 176/2004, which established the statutes of the Spanish National Centre for Transplants and Regenerative Medicine, the *Centro Nacional de Trasplantes y Medicina Regenerativa (CENTMER)*[34] In other word, the discourses were no longer framed in terms of xenotransplantation as opposed to other solution, but much more generally within a wider framing of regenerative medicine.

The Spanish Ministry of Health (MSC), together with the Autonomous Communities, approved the creation of three research centres for regenerative medicine (July 2004):

- Catalonia (CMRB)
- Andalusia (CABIMER)
- Valencia (Centro de Investigación Príncipe Felipe)

The basic task of these centres is to carry out research with human embryonic stem cells and different animal models in order to understand:

- The basic mechanisms of initial development and organogenesis.

[32] http://www.vatican.va/roman_curia/pontifical_academies/acdlife/documents/rc_pa_acdlife_doc_20010926_xenotrapianti_en.html

[33] It is worth reminding the reader that in Italy the legislative void on assisted reproduction and human embryos ended after 2 decades by the law 40/2004 that imposes one of the most restrictive regulatory frameworks.

[34] http://www.gencat.cat/salut/depsalut/html/en/dir212/doc7091.html

- Application of the cell lines derived from stem cells to diseases (regenerative medicine) in which there is a loss of cells (degenerative diseases).[35]

In September 2004, the Council of Ministers appointed Rafael Matesanz as the director of CENTMER with the explicit mandate of strengthening the international standing of the centre in the light of the favourable view of the World Health Organisation of making Spain the locus for a World Transplantations Register.[36]

With permissive regulations on xenotransplantation already in place for a long time and the changes in national policies on embryonic stem cell research brought about in 2003 and 2004 there do not seem to have been important national policy initiatives in Spain, not taking into account the consolidation of coordination of research into regenerative medicine. It is tempting to interpret this in the terms of policy action shifting to the EU level with the preparation of the Advanced Therapy Medicinal Products (1349/2007)[37]

5.3.3 Public consultation – and overview/summary of socio-cultural dimensions

Along with many other European countries Spain has been experimenting with new forms of public participation in technology assessment in recent years. As far as evidence could be collected for this report, efforts at involving the public have for the most part regarded environmental issues on a local level. In such cases participation has been primarily through Civil Society Organisations. Public consultations in matters relating to health care or medical research have mostly been through the involvement of organisations of patients and their families. There is, however, no evidence to suggest that any novel forms of experimentation with participatory approaches have ever been applied to the issue of xenotransplantation as such.

Broadly speaking, pertinent citizens seem to have been for the most part defined in the debate as patients awaiting organ transplants and their family and friends. The Spanish National Guidelines explicitly mention the importance of eventual recipients and their families being made fully aware of the risks involved and further, given the novelty of this approach that they will be made to appreciate the need for continuous monitoring into the future with the all the restrictions upon private lives that such surveillance would entail.

Spain has undergone profound political changes in recent decades most notable being the decentralisation and regionalisation of powers, particularly important in terms of policies on

[35] http://www.cmrb.eu/que-es/en_missio.html
[36] http://www.msc.es/gabinetePrensa/notaPrensa/desarrolloNotaPrensa.jsp?id=127
[37] the EC directive 1394/2007 on Advanced Therapy Medicinal Products explicitly states: *"The regulation of advanced therapy medicinal products at Community level should not interfere with decisions made by Member States on whether to allow the use of any specific type of human cells, such as embryonic stem cells, or animal cells. It should also not affect the application of national legislation prohibiting or restricting the sale, supply or use of medicinal products containing, consisting of or derived from these cells"*http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:324:0121:0137:en:PDF

health and medical research. Further, many analysts note the underlying tensions between the secular tradition of views on humans and human nature as exemplified by the Catholic Church and its relationship with national politics and political forces that attempt to redefine the basic institutions of Spanish society.

An interesting perspective on the changes in Spanish society is provided by the highly idiosyncratic films by Pedro Almodovar where organ transplants and the nature of human identity have been recurring themes for a long time.

5.3.4 Conclusions

In short, Spain was one of the forerunner in the development of xenotransplantation with excellent network of organ transplantation services already in place across the country and the right regulatory framework, national guidelines on clinical trials were published early on, Spain was the first country to oppose the proposed moratorium on clinical trials and the Spanish public that has traditionally been receptive to biotechnology, in particular biomedical applications.

Further, the seems to have been broad political consensus in the country over the last three decades that investing in science and technology would not only bring the country in line with other major European countries but there has also been a strong impetus to create centres of excellence. Given the historically strong ties to Central and South America and increasing Ibero-American collaborations, it is reasonable to assume that policy developments in the field of regenerative medicine in Spain would have ramifications well beyond the borders of the European Communities.

As in most EU member states the narratives of policy making tend to bounce back between European and national levels. The Advanced Medical Products Directive The EC directive 1394/2007 firmly embedded in a subsidiary principle should now put Spain in a pole position in the development in various fields of regenerative medicine with a permissive national regulation on stem cell research and xenos and therefore, presumably, on various combination of sources of therapeutic options.

5.3.4.1 Concluding Discussion of Policy Process – Country Chart Spain

Country Spain	**1990 - 1999**	**1999-present**
Principle regulatory Authority	Statutory: Ministry of Health and Consumer Affairs. Advisory: Comisión Permanente de Trasplantes del Consejo Interterritorial del Sistema Nacional de Salud, Organización Nacional de Trasplantes, Ministerio de Sanidad y Consumo 1998: Subcomsión de xenotrasplante de la Comisión Permanente de Trasplantes del Consejo Interterritorial del Sistema Nacional de Salud, Organización Nacional de Trasplantes, Ministerio de Sanidad y Consumo	Subcomsión de xenotrasplante de la Comisión Permanente de Trasplantes del Consejo Interterritorial del Sistema Nacional de Salud, Organización Nacional de Trasplantes, Ministerio de Sanidad y Consumo (2004) Centro Nacional de Trasplantes y Medicina Regenerativa (CENTMER)
Principal policy	Strong tradition of organ donation (highest in the world) Permitted – "Xenotrasplante", . Subcomisión de Xenotrasplante de la Comisión Permanente de Trasplantes del Consejo Interterritorial del Sistema Nacional de Salud Organización Nacional de Trasplantes, Ministerio de Sanidad y Consumo, 1998, Madrid	Permitted – through clinical trial route
Public consultations	Hard to find any evidence of public consultation Eurobarometer survey 1996	Eurobarometer survey 1999, 2002 and 2005 BBV survey on public views

	BBV survey 1997	on stem cell research and hybrid embryos, 2008
Dominant consultative features	Impermeable: Expert-led advisory committees - Closed meetings - Little or no evidence of policy-led consultation beyond written submissions to advisory committees. Porous: In recent years Spain has been experimenting with novel forms of public consultation mostly acted out on a regional level given the semi-federal organisation of the country. However, such attempts have mostly regarded environmental issues and the interlocutors tend to be organisations (such as NGOs) rather than individual citizens. By the same token, when it comes to health and medical research the only notable development is the increased involvement of patient groups and their families in trying to get a voice in policy matters. Permeable: Academic-led, poorly organised and coordinated and therefore yields little influence – very poorly embedded in policy-making	
Key cultural features	Strongly polarised: Historically strong institutionalisation of ethical views that emphasise the *sanctity* of human life in all natural stages (forbids the use of human embryos for purposes other than reproduction), that places a high value on solidarity, charity and "the gift of life" (promote organ transplants but forbid all form of commercialisation) and places the wellbeing of humans over those of other living creatures. On the opposite end, "modernising" forces that herald cutting edge biomedical research and eventual new treatments as almost the emblem of progress and in many instances attempts to put into question profoundly rooted notions of human identity and the relationship between society and nature. Policy developments in biomedical science in Spain tend to reverberate across the Spanish speaking, predominantly Roman Catholic parts of the world.	

5.4 Nordic countries: Denmark, Norway and Sweden

Kristofer Hansson, Susanne Lundin

5.4.1 Denmark: 2001-2002

5.4.1.1 Introduction and Methods

In Denmark, basic research in XTP has been done for the last 20 years.

Neither clinical trials on humans, nor XTP from pigs to apes have been conducted.[38] In the 90s the Royal Veterinary and Agricultural University started a project in order to create transgenic pigs for XTP and a working group, *Danish transgenic pig study group,* was formed. When the international climate became more negative to XTP this research area was reduced in Denmark but it did not entirely stop. There are no findings on the Internet concerning what kind of XTP research Denmark has in the field today.

Clinical trials in Denmark are regulated by The National Board of Health guidance from 1999, which regulates the introduction of new treatments.[39] In 2001 a debate started in the Danish Parliament leading to the decision that no treatments or experiments on humans with animal cells and tissues were allowed until the public authorities had given their permission. In other words, the debate began rather late in Denmark. In addition, when the OECD held their international debate about XTP in New York in 1998 all Nordic countries were represented except Denmark.[40] Why did the debate start so late in Denmark?

The methods applied in producing this review largely depend on the analysis of published and grey literature. The material stretches back to the beginning of the 21st century. The published and grey literature is all produced by the Danish government. The report "The biotechnologies of the Future – Possibilities and risks"[41] from 2002 has been a key text in the analysis.

5.4.1.2 Overview of landmark developments and timeline – Key features of policy-making and process

On January 22nd 2001 the Danish Council of Ethics and The Danish National Committee on Biomedical Research Ethics made a common statement directed to all regional Council of Ethics calling for all issues related to the preparation of and practice of XTP experiments to

[38] Ministeriet for Videnskab, teknologi og udvikling (2002). *Fremtidens bioteknologier – muligheder og risici*. København: Videnskabsministeriet.
[39] Ministeriet for Videnskab, teknologi og udvikling (2002). *Fremtidens bioteknologier – muligheder og risici*. København: Videnskabsministeriet.
[40] Se: http://islet.org/34.htm.
[41] Ministeriet for Videnskab, teknologi og udvikling (2002). *Fremtidens bioteknologier – muligheder og risici*. København: Videnskabsministeriet.

be submitted to the Danish Council of Ethics.[42] At the same time the Ministry of Welfare in the Danish Parliament and The National Board of Health informed the county council and the Association of Hospitals in the capital of Denmark that no treatment with XTP was allowed but that experiments could be approved.[43] The statement and the message started a debate in the Danish Parliament in January. The Christian Democrat Tove Videbæk presented the following dilemmas:

> This complex of problems and more so are the ground for that I on behalf on Christian Democrats want to ask […] how the government will guarantee that research in and experiments with xenotransplantation will take place only if the necessary safety is in place, that possible experiments exclusively is taken place in controlled and restricted events, and that the donate- and experiment animal welfare will be carefully considered.[44]

On the basis of the debate the Danish Parliament decided that no treatments or experiments should be allowed until the public authorities had given their permission. In consultation with the other ministers the Minister for Science, Technology and Innovation appointed a commission to map out the risks associated with the new bio- and gene technologies such as gene diagnostics, gene therapy, therapeutic cloning and XTP.[45] Additionally, the Danish Parliament decided that the Danish regulations should relate to the international development on the subject and be matched to those proposals for guiding principles that the Council of Europe had been working with since the beginning of 2000. In extension of the Danish Parliament decision the National Board of Health sent out a communication on May 30, 2001 to the county council and the Association of Hospitals in the capital of Denmark stating:

> … treatments with xenotransplantation at country hospitals shall not be performed without a science ethics report, in which after evaluation approval of the scientific direction is given, until a legislation or an outline of the public authorities is established in detail with rules creating clear frames for the treatment in detail.[46]

The National Board of Health also pointed out that Denmark at the time did not need an extensive and independent inquiry specifying the practical implementation of national rules since XTP at the time was not a realistic treatment. Issues related to experiments and preparation for experiments with XTP should be submitted to the Danish Council of Ethics in

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[42] Ministeriet for Videnskab, teknologi og udvikling (2002). *Fremtidens bioteknologier – muligheder og risici*. København: Videnskabsministeriet.
[43] Ministeriet for Videnskab, teknologi og udvikling (2002). *Fremtidens bioteknologier – muligheder og risici*. København: Videnskabsministeriet.
[44] 2000-01 - F 11 BEH1 tirsdag 30 januar 2001, Tale 1, TOVE VIDEBÆK (KRF).
[45] Ministeriet for Videnskab, teknologi og udvikling (2002). *Fremtidens bioteknologier – muligheder og risici*. København: Videnskabsministeriet.
[46] Ministeriet for Videnskab, teknologi og udvikling (2002). Fremtidens bioteknologier – muligheder og risici. København: Videnskabsministeriet.

accordance with the common statement from the Danish Council of Ethics and The Danish National Committee on Biomedical Research Ethics from January 22, 2001, which is equal to the law about biomedical projects § 7 stk. 4.[47]

In October 2002 the Minister for Science, Technology and Innovation published the report "The biotechnology's of the Future – Possibilities and risks"[48] stating "[…] the Danish Parliaments decision from January 30, 2001 and The National Board of Health's communication from May 30, 2001 have in a satisfactorily way regulated the area to guarantee that xenotransplantation is performed as scientifically projects after approval in the Danish Council of Ethics" (p. 87).[49]

5.4.1.3 Public consultation – and overview/ summary of socio-cultural dimensions

In March 1999 BIOSAM (a Danish organization for consultation and creating debate around biotech questions), in cooperation with University of Copenhagen, arranged an expert meeting about XTP in Denmark.[50] Four experts were invited to talk about XTP: Jan Ottesen from NOVO Park A/S, Gustav Groth from Karolinska University, Robin A. Weiss from Chester Beatty Laboratories and D.K.C. Cooper from Massachusetts General Hospital. The aim of the meeting was to start off a Danish debate about XTP and the debate came to focus on how the risks with XTP could be managed. In the summary of the meeting BIOSAM notes: "BIOSAM is of the opinion that there are reasons to focus on the question marks and problems that xenotransplantation raise. In order to create a ground for a standpoint BIOSAM will therefore arrange a hearing in the subject".[51]

In the beginning of 2000 the hearing was held in the Danish Parliament.[52] It was the Danish Board of Technology and The Danish Council of Ethics that arranged the hearing about XTP prepared by BIOSAM. The aim of the meeting was to inform the members of the Danish Parliaments of the possibilities and risks associated with XTP. The presentations were all held by experts from Denmark and Sweden. The consultation was confined to involve experts and politicians.

The importance of consultation to the public is highlighted in the report "The biotechnology's of the Future – Possibilities and risks" in which the importance of a debate about new biotech technologies is emphasized by the following statement: "The Committee has with this report tried to give an academic foundation and has also identified several problem areas, which

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[47] § 7 stk. 4 Lov om et videnskabsetisk komitésystem og behandling af biomedicinske forskningsprojekter.
[48] Ministeriet for Videnskab, teknologi og udvikling (2002). *Fremtidens bioteknologier – muligheder og risici*. København: Videnskabsministeriet.
[49] Ministeriet for Videnskab, teknologi og udvikling (2002). *Fremtidens bioteknologier – muligheder og risici*. København: Videnskabsministeriet.
[50] Se: http://www.tekno.dk/pdf/9907nr1.pdf.
[51] http://www.tekno.dk/pdf/9907nr1.pdf.
[52] 24-02-2000: Høring om xenotransplantation. www.tekno.dk. Se also the report: http://www.tekno.dk/pdf/projekter/p00_xeno.pdf.

would require public debate and a political standpoint".[53] We could not find any examples of public consultation about XTP in Denmark in the beginning of the 21st century, probably because the focus changed from XTP to other bio- and gene technologies at this time. The key features of policy making in Denmark must be classified as expert-based consultation, but the public consultation is highlighted in many of the reports about XTP.

5.4.1.4 Country chart

Country Denmark	**1990 - 2000**	**2000-present**
Principle regulatory Authority	The National Board of Health. Consultative agency: Danish Council of Ethics and The Danish National Committee on Biomedical Research Ethics.	The National Board of Health. Consultative agency: Danish Council of Ethics and The Danish National Committee on Biomedical Research Ethics.
Principal policy	The National Board of Health guidance from 1999.	2001: The Danish Parliament decided that no treatments or experiments were allowed without permission from the public authorities.
Public consultations	None	None
Dominant consultative features	Consultative agency with experts and politicians. The public consultation is highlighted in many of the reports about XTP. The consultation did not start, probably because the focus changed from XTP to other bio- and gene technologies in the beginning of 2000.	
Key cultural features	Denmark is in many ways a pioneer in "public engagement with science".[54] This is highlighted in many of the reports about bio- and gene technologies. Highly developed approach to biotech.	

[53] Ministeriet for Videnskab, teknologi og udvikling (2002). *Fremtidens bioteknologier – muligheder og risici*. København: Videnskabsministeriet.
[54] Mejlgaard, N. (2009) The trajectory of scientific citizenship in Denmark: changing balances between public competence and public participation. In: *Science and Public Policy*, 36(6), pp. 483-496.

5.4.2 Norway: 1999-2009

5.4.2.1 1. Introduction and Methods

No information about clinical trials or basic research in XTP conducted by medical scientists in Norway has been found. Still, in the end of the '90s the Ministry of Health and Care Services distributed a report for consideration about changes in transplantation law. The report included a proposal to impose a temporary admission ban of XTP as well as an establishment of a committee for evaluation of XTP. In the beginning of the 20th century Norway seemingly had a big interest in XTP as a medical technology for the coming future. The report was issued in 2001 and it is obvious that Norway really wanted to develop this new technology and simultaneously build up knowledge in order to make it possible to control the risks connected to XTP.[55]

In contrast to this, Norway is the only Nordic country which has experienced a strong negative public reaction against XTP. A political discussion about policy-making about XTP has taken place in Sweden and Denmark but the public have not taken part in this discussion. The Norwegian reaction to XTP came in 2006 when the Ministry of Health and Care Services sent out a proposal for a law regulating the use of XTP.

The methods applied in producing this review largely depend on analysis of published and grey literature. The material stretches from 1999 up to the end of 2009. The published and grey literature is all produced by the government in Norway. The report "Xenotransplantation. Medical use of living cells, tissue and organs from animals"[56] from 2001 has been a key text in the analysis.

5.4.2.2 Overview of landmark developments and timeline – Key features of policy-making and process

Clinical XTP trials were forbidden by law until January 1, 2009.[57] The law came into force on July 1, 2001 and was very specific: "Transference of living biological material from animals to human beings is not allowed".[58] Already in the report "About people and biotechnology"[59], from the beginning of the 90s, it was emphasised that there should be "a broad inquiry about the ethical, medical and animal questions if (…) transplantations of organs from gene modified animals to humans become topical" (p. 141). In August 16, 1999 the Ministry of

[55] NOU 2001:18 "Xenotransplantasjon. Medisinsk bruk av levende celler, vev og organer fra dyr". Oslo: Statens forvaltningstjeneste Informasjonsforvaltning.
[56] NOU 2001:18 "Xenotransplantasjon. Medisinsk bruk av levende celler, vev og organer fra dyr". Oslo: Statens forvaltningstjeneste Informasjonsforvaltning.
[57] Innst. O. nr. 5 – 2007-2008.
[58] § 6a. Overføring av levende biologisk materiale fra dyr til mennesker er ikke tillatt.
Tilføyd ved lov 8 juni 2001 nr. 31 (i kraft 1 juli 2001 iflg. res. 8 juni 2001 nr. 567), endret ved lov 19 des 2008 nr. 111.lov 9. februar 1973 nr. 6 om transplantasjon, sykehusobduksjon og avgivelse av lik m.m.
[59] St.meld. nr. 25 (1992-93) Om lov om medisinsk bruk av bioteknologi.

Health and Care Services distributed a report for consideration about changes in the law regarding transplantation. The report included a proposal to impose a temporary admission ban on XTP until January 1, 2003.[60] In addition, the establishment of a committee for the evaluation of all sides of XTP was proposed.[61] The XTP committee delivered the report "Xenotransplantation. Medical use of living cells, tissue and organs from animals" in June 2001.[62] After the publication of the report Norway established an authority responsible for supervising XTP on a national as well as an international level. The authority was established in 2003 and it has delivered four reports between 2004 and 2006.[63]

On November 7, 2006 the Ministry of Health and Care Services published a report about a proposal of a law regulating the use of living material from animals for the medical treatment of humans.[64] The proposal was based on EU guiding principles for XTP and those recommendations that were presented in the report "Xenotransplantation, Medical use of living cells, tissue and organs from animals". The report was referred to selected bodies for consideration and the Ministry received 36 statements of which about 50 percent were in opposition to the proposal. Due to the high degree of resistance, an extension of the temporary admission ban of XTP with one year, until January 1, 2009 was proposed.

On November 15, 2007 the Ministry of Health and Care Services issued an advisory report to stop the law forbidding XTP.[65] It states:

> Not at least as a consequence of the international progress where several large firms have cancelled or reduced their investments on xenotransplantation lately, the department imply that it is still reasonable to assume that xenotransplantation will not be taken in practise in an enhanced amount in the near future, neither in an established treatment or in clinical trials. It is also commented that it is highly uncertain if xenotransplantation will be taken in practise in Norway and in that case when this is likely to occur. The department also wants to point out that on an international level there are not many countries that have seen a need to regulate xenotransplantation in the law (p. 1).

Norway seems to have had a stronger national discussion about XTP than Sweden or Denmark, which might be a consequence of the country not being a member of the European Union. While Sweden has moved the discussion to more international arenas

[60] NOU 2001:18 "Xenotransplantasjon. Medisinsk bruk av levende celler, vev og organer fra dyr". Oslo: Statens forvaltningstjeneste Informasjonsforvaltning.
[61] kgl. res. 3. desember 1999.
[62] NOU 2001:18 "Xenotransplantasjon. Medisinsk bruk av levende celler, vev og organer fra dyr". Oslo: Statens forvaltningstjeneste Informasjonsforvaltning.
[63] Halvårsrapport fra helsedepartementets interimsorgan for xenotransplantasjon 1. Februar 2004; Halvårsrapport fra helsedepartementets interimsorgan for xenotransplantasjon 1. August 2004; Årsrapport fra helsedepartementets interimsorgan for xenotransplantasjon 15. Desember 2005; Årsrapport fra helsedepartementets interimsorgan for xenotransplantasjon 15. Desember 2006. www.regjeringen.no.
[64] Høyringsdokument, 07.11.2006. Forslag til lov om bruk av levende biologisk materiale fra dyr ved medisinsk behandling av mennesker (Xenotransplantasjonsloven). Helse- og omsorgsdepartementet.
[65] Innst. O. nr. 5 – 2007-2008.

Norway has created its own authorities to discuss XTP. Hence, it may be interesting to ask questions about how citizen participation has been affected by the fact that Norway is not a member of the EU.

5.4.2.3 Public consultation – and overview/ summary of socio-cultural dimensions

When the report "Xenotransplantation. Medical use of living cells, tissue and organs from animals"[66] was under production, the XTP committee invited experts to the meetings. Many of the experts were from Sweden, e.g. the leader for the Swedish Committee on XTP Bertil Persson, senior physician Annika Tibell, associated professor Stellan Welin and so forth. The group also made a study visit to England to learn more about UKXIRA (United Kingdom Xenotransplantation Interim Regulation Authority) and to study Novartis Imutran. No public consultation had been conducted at the time that the report was produced. Yet, the importance of having openness to society about the risks associated with XTP was pointed out by the group in the report: "Since xenotransplantation theoretically can have a damage effect for all people – not only the patients - there ought to be big demands on openness and insight" (p. 12).

The reaction in Norway to XTP came in 2006 when the Ministry of Health and Care Services sent out a proposal for a law regulating the use of living material from animals in medical treatment of humans. The Ministry received 36 statements in which different organisations commented on the law. In addition, the Ministry received an organized e-mail from 34 persons who wanted to stop XTP in Norway. This e-mail is of great importance since it adds to the perspective on how people can express disapproval of XTP:

> "To Health and Care Services Minister Sylvia Brustad.
>
> I do not want xenotransplantation to be carried out in Norway!

Clinical trials with xenotransplantation have already claimed the life of thousands of animals, and will require far more if it is accepted as a treatment. This is contrary to Parliament's objective from 2003 of a reduction in the number of animals used in experiments. All animals have intrinsic value. With xenotransplantation the animals lose this intrinsic value and become "factories of reserves". Experiments are themselves painful and stressful for the animals. In addition, the environment will be restrictive and the living space limited. The life as an organ donator deprives the animal's ability to natural behaviour, and leads to mental and physical disorders. Over the last hundred years, several attempts have been made to transplant organ from animals to humans. All have failed. There is no evidence that xenotransplantation can function as a treatment. To transplant involves also risk of

[66] NOU 2001:18 "Xenotransplantasjon. Medisinsk bruk av levende celler, vev og organer fra dyr". Oslo: Statens forvaltningstjeneste Informasjonsforvaltning.

transferee highly dangerous virus, both to the organ recipient and to the rest of the society".[67]

The consequence of this kind of opposition to XTP was a proposal from the department implying an extension of the prohibition against XTP of one year.

The key features of policy making in Norway must be classified as expert-based consultation. The system can in this way be defined as *impermeable*: it is solution-led and focuses mostly on the technology. What can be interpreted as exceptional is the expression of disapproval of XTP in Norway. Why do we see this in Norway and not in Sweden and Denmark?

[67] Høyringsdokument, 07.11.2006. Forslag til lov om bruk av levende biologisk materiale fra dyr ved medisinsk behandling av mennesker (Xenotransplantasjonsloven). Helse- og omsorgsdepartementet.

5.4.2.4 Country chart

Country Norway	**1990 - 2000**	**2000-present**
Principle regulatory Authority	The Ministry of Health and Care Services. Advisory: None.	The Ministry of Health and Care Services. Advisory: Norway's Committee on XTP started 2003.
Principal policy	1999 the Ministry of Health and Care Services distributed a report for consideration about changes in law of transplantation. The report included a proposal of imposing a temporary admission ban of XTP until 2003.	Law forbidding clinical XTP trials between 2001-2009.
Public consultations	None.	2006: Ministry of Health and Care Services issued a report about a proposal of a law regulating the use of living material from animals at medical treatment of humans distributed as a proposal for consultation to selected bodies.
Dominant consultative features	Consultative agency with experts and politicians. Closed meetings. Impermeable: it is solution-led and focuses mostly on the technology. What can be interpreted as exceptional is the expression of disapproval of XTP in Norway.	
Key cultural features	Do not have a highly developed approach to biotech. Focus on animal welfare.	

5.4.3 Sweden: 1990-2003

5.4.3.1 Introduction and Methods

Between 1990 and 1993 researchers at Karolinska University Hospital, Huddinge, carried out clinical trials in which ten patients with diabetes underwent transplant surgery with pig cells producing insulin. Two years later, 1995, researchers at Sahlgrenska University Hospital, Gothenburg, connected a pig kidney to a patient. For 1 hour and 15 minutes the human blood streamed through the kidney. At this time Sweden had between 10 and 15 scientist groups working with XTP. A project called "Xenotransplantation in Gothenburg before year 2000" was established in Gothenburg. The Swedish media reported the trials in a very favorable manner.[68] In the beginning of 1996 the politician Bertil Persson from the Conservative party pointed out to the Swedish Parliament that the issue of XTP would develop and result in a complicated debate in the coming years.[69] This is a starting point in the Swedish debate about policy process around XTP. One year later a moratorium for XTP was imposed and a Committee report stated that a Committee on XTP should be appointed.[70] The Minister for Health and Social Affairs Margot Wallström, Social Democracy party, declared that XTP is raising such big ethical questions that the regular ethical committee could not approve continuing clinical trials on humans.[71] In 2009 there are still no new clinical trials in Sweden. What happened in the mid 1990[s]?

The methods applied in producing this review largely depend on analysis of published and grey literature as well as on analysis of articles in newspapers and news on TV. The material stretches from 1995 to the end of 2003. The published and grey literature is all produced by the Swedish government. The newspaper articles are from The Swedish news agency or from the bigger newspapers in Sweden. The articles have been analysed in depth in Hansson 2003 and 2005.[72]

5.4.3.2 Overview of landmark developments and timeline – Key features of policy-making and process

A legal framework making it possible to perform limited XTP trials in Sweden has been proposed although it has not yet been presented to the Parliament.[73] A moratorium for XTP came in 1997 and at the same time a Committee report stated that a Committee on XTP

[68] Hansson, K. (2003). Djur som donatorer. Xenotransplantation i svenska medier 1995-2002. In: *Lundalinjer*, nr 120.
[69] Protokoll 1996/97:77.
[70] Kommittédirektiv 1997:44 "Överföring av organ och vävnad från djur till människa".
[71] Överföring av djurorgan till människa utreds. In: TT Nyhetsbanken, 1997-03-06.
[72] Hansson, K. (2003). Djur som donatorer. Xenotransplantation i svenska medier 1995-2002. In: *Lundalinjer*, nr 120; Hansson, K. (2005). Biopop. Biovetenskapens popularisering i medierna. I: *ETN. Etnologisk skriftserie* nr 1, 107-117.
[73] Tibell, A. and Lundgren, T. (2004). Xenotransplantation – Clinical Activities and Regulatory Development. In: *Acta Veterinaria Scandinavica*, 45(Suppl 1), p. 19-23.

should be appointed in Sweden.[74] The Swedish Committee on XTP started in the form of a consultative agency led by the politician Bertil Persson. Besides politicians, the committee consisted of experts from different fields. The Committee presented their thoughts in the Swedish Government Official Report "From One Species to Another".[75] This was submitted to the Swedish Minister of Health in 1999 with proposals concerning ethical, medical, legal and animal welfare aspects of XTP. The report is at present in consideration at the Government Offices of Sweden and the moratorium for clinical trials is still in operation.

Between 1997 and 1999 there was an intense discussion in Swedish media about XTP. Before 1997 it was only scientists working with XTP who presented their perspectives in media. Following the moratorium, politicians and scientists in the humanities started to express their views. At this time the scientists working with XTP began to feature their perspective from a more political angle. The border between science and politics became fluid; scientists expressed opinions about policy-making and politicians expressed views about science.[76]

After the publication of the report "From One Species to Another" the open discussion about policy-making questions and XTP in Sweden became increasingly quiet. From 1999 the political discussion about XTP in Sweden seems to take place in the Steering Committee on Bioethics (CDBI). This was the first year Sweden reported about the policy-discussion at CDBI in a document.[77] The reports from CDBI about XTP continued to 2003. The Green Party submitted a motion at the end of 2000 trying to create a discussion about policy-making and XTP, but the motion was rejected and there was no further discussion.[78] Media coverage of XTP also declined (from 29 articles in 1999 to 14 articles in 2001).[79] So if Sweden more or less had a national discussion about policy-making at the end of the 90^{s}, the policy discussions appear to have moved to international arenas since then.

In the report from the Committee on XTP it was pointed out that experiments on animals regarding XTP should be performed within the frame of the Animal Welfare Act in consideration.[80] If there is any XTP research in Sweden today, it seems to fall within the Animal Welfare Act. There is still an agreement among the scientists about a moratorium regarding clinical trials of XTP. In addition, experiments on animals regarding XTP have been discussed in the Swedish political arena following publication of the report.[81] This is a political arena in which the Christian Democrats submitted a motion in 2003 expressing the importance of a debate concerning XTP. The party wrote that it is: "[…] not acceptable that

[74] Kommittédirektiv 1997:44 "Överföring av organ och vävnad från djur till människa".
[75] SOU 1999:120 "Från en art till en annan. Transplantation från djur till människa". Betänkande av xenotransplantationskommittén.
[76] Beck, U. (1992). *Risk Society. Towards a New Modernity*. London: Sage Publications Ltd.
[77] Skrivelse 1998/99:55 Redogörelse för verksamheten inom Europarådets ministerkommitté under år 1998.
[78] Motion 2000/01:So533 Xenotransplantationer.
[79] Hansson, K. (2003). Djur som donatorer. Xenotransplantation I svenska medier 1995-2002. In: *Lundalinjer*, nr 120.
[80] SFS 1988:534.
[81] Written communication from the Government 2001/02:48; Swedish Government Official Report 2003:107.

an animal is bred up solely to be a reserve storage for human beings, if it undermines the animals possibilities to a natural behaviour or if the result of the strange organ is reduced wellbeing".[82] The motion was rejected and there was no further discussion regarding XTP.[83]

It is important to ask whether the Swedish Government did not want a national discussion at the beginning of the 21st century or whether XTP was simply not a political question of importance in Sweden at that moment. Additionally, how has this in turn affected the citizen participation in Sweden?

5.4.3.3 Public consultation – and overview/ summary of socio-cultural dimensions

The policy process in the middle of the 90s had the features of expert-based consultation when the Swedish Committee on XTP started. The committee was closed but there were public consultations. In 1998 the result of a public opinion survey on XTP was presented. The result was also something that interested the media. The Swedish TV-news produced an item in which it was pointed out that the Swedes were in favour of XTP and continuing clinical tests.[84] Instead of asking people on the streets about XTP the media used the results from the survey. Thus, the media also focussed on the experts when reporting about XTP. The result of the survey was presented in the report "From One Species to Another".

In November 1998 the Swedish Gene Technology Advisory Board arranged a Swedish conference about XTP with about 250 participants.[85] The aim of the conference was to start off a Swedish discussion about the possibilities and risks associated with XTP. The presentations were all conducted by experts from different fields. The Swedish public opinion survey on XTP was presented at the conference as well as public opinion surveys done in other countries. Ethnologist Susanne Lundin presented her study based on interviews of eight of the ten patients with diabetes who underwent transplant surgery with pig cells in the beginning of 90s.[86]

When the report "From One Species to Another" was published it was distributed for consultation to selected bodies whereof most recommended that XTP should be allowed in well controlled clinical trials, had a limited extent and in which the risks where estimated to be controllable. In Sweden this is the most common way to get public consultation in policy questions.

Even if Sweden had some public consultation in the 90s the key features of policy making in Sweden must be classified as expert-based consultation. Looking at the media we can see

82 Motion 2003/04:MJ367 Djurskydd.
83 2003/04:MJU14.
84 Rapport 1998-11-20: 17.00-17.05 (TV News).
85 Spri-rapport 489: Xenotransplantation: från djur till människa. Möjligheter och risker: rapporten dokumenterar en konferens, som ägde rum 20 november 1998 i Riksdagensandrakammarsal, Stockholm. Stockholm : Spri.
86 se also: Lundin, S. and Widner, H. (2000). Patientröster om xenotransplantation: «Jag skulla göra allt, för jag vill inte dö!» In: Läkartidningen, 97: 1940-1943.

that in many ways, media bodies were also acting as if the Swedish system is expert-based by interviewing only experts in XTP and politics. The Swedish system can in this way be defined as *impermeable*: it is solution-led and focuses mostly on the technology. What can be interpreted as exceptional is that the Swedish politicians seemingly want to take the discussion about XTP policy to an EU-level.

5.4.3.4 Country chart

Country Sweden	**1990 - 2000**	**2000-present**
Principle regulatory Authority	Swedish Minister of Health. Advisory: the Swedish Committee on XTP (1997-1999).	Swedish Minister of Health. Advisory: CDBI (1999-2003).
Principal policy	Moratorium from 1997 to present – an agreement among the scientists. From 1999 possible to do XTP-research on animals in consideration of the Animal Welfare Act.	There is still an agreement among the scientists about a moratorium regarding clinical trials of XTP.
Public consultations	1998: Public opinion survey on XTP. 1998: Swedish Gene Technology Advisory Board arranged a Swedish conference about XTP. 1999: The report "From One Species to Another" was distributed as a proposal for consultation to selected bodies.	see Lundin and Idvall 2003.[87]
Dominant consultative features	Consultative agency with experts and politicians. Closed meetings. Impermeable: it is solution-led and focuses mostly on the technology.	

[87] Lundin, S. and Idvall, M. (2003). Attitudes of Swedes to marginal donors and xenotransplantation. In: *Journal of Medical Ethics*, 29, 3, 186-192.

	In the end of the 90^{s} there seems to be a change in the Swedish debate on the issue and more of the consultative discussion moved to the EU-level.
Key cultural features	The Swedish culture is characterized by the ambition of being on the cutting edge of new technologies. Highly developed approach to biotech. Focus on animal welfare.

5.5 The UK

Nik Brown and Siân Beynon-Jones

5.5.1 Introduction and Methods

For UK science policy-making, the xenotransplantation case lies at the centre of deep-rooted tensions in the public appraisal of new developments in the biosciences.

In recent decades successive governments have taken commercial biotechnology to illustrate the route towards international competitiveness within newly developing commercial sectors. In terms of an explicitly neoliberal economic rationale, the place of the state has been seen to be progressively more facilitative rather than regulative and/or restrictive. However, the government's favourable disposition towards the biosciences has not been matched by either the general tone of media reportage or by the reputational standing of the bioindustries amongst the public, however broadly conceived. During the 1990s, controversy over xenotransplantation ran in parallel with the double crisis of the BSE disaster and then later, the GM debate, both of which were unmistakably acute in the UK. Both events were taken to signal the fundamental requirement for institutional change in fostering greater public trust through engagement and transparency. The GM crisis in particular was used to point to the need for a more "up stream" anticipatory consultative ethos and the importance of avoiding normative policy preferences in advance of public discussion (Wilsdon and Willis 2004).

The review that follows was produced through a detailed analysis of secondary gray literature stretching back over the course of the last two decades to the end of the 1980s. This includes:

- Public engagement and opinion surveys where xenotransplantation has been either the central or peripheral objective within the study;
- Social and political science commentary seeking to characterise the dynamics of engagement and citizenship within UK science policy;
- Reviews and commentary on the changing institutional characteristics of regulation pertaining to xenotransplantation in the UK, including non-governmental advisory reports.

5.5.2 Overview of landmark developments and timeline/key features of policy making and process

5.5.3 Formation of UKXIRA

For the UK, the presence of commercial research activity throughout the early 1990s served as a primary source of motivation for the establishment of regulatory oversight. In 1993 the

Cambridge-based company Imutran announced the birth of the first transgenic pig immunologically altered to reduce the severity of tissue rejection when transplanted into humans. Throughout the mid 1990s a steady stream of news and media announcements kept xenotransplantation in the public eye. By 1999 Imutran had formally stated its intention to apply for and conduct clinical trials in 2000, adding greater urgency to the need for regulation.

The end of the 1990s saw a succession of regulatory initiatives, beginning in 1996 with the report of the Nuffield Council on Bioethics Chaired by Prof. Albert Weale, then professor of government at the University of Essex. The Committee was an interdisciplinary body with strong representation from across the natural and social sciences and humanities. Its report, published in March 1996, called for a precautionary approach to be taken with respect to the high degree of uncertainty surrounding transpecies disease, particularly given the prevailing controversy at that time surrounding BSE. The method of consultation was typical of the passive approach used throughout the 1990s: formal announcement of a consultation period in which individuals and institutions would be invited to submit written statements for consideration by the panel.

Within months the UK Department of Health had also commissioned a panel of experts to comprise the "Advisory Group on the Ethics of Xenotranplantation, Animal Tissues into Humans" under the chairmanship of Sir Ian Kennedy. Again, the consultation involved an open invitation canvassing for written statements. The Kennedy report was published in 1997 and concluded that xenotransplantation was acceptable in principle if certain preconditions were met. These included the establishment of a national regulatory body (1997, 5.4) to act as a central focal point for intelligence about the development of the technology and the risks associated with it. The report stated that this regulatory body should have the statutory authority to take decisions independently of the political executive.

In the wake of the BSE crisis in the late 1990s there were new pressures on advisory and regulatory bodies to reflect a broader range of expertise in their proceedings (OST, 2000). It was within this wider climate that the United Kingdom Xenotransplantation Interim Regulatory Authority (UKXIRA) was instituted on the heels of the Kennedy Report in 1997. UKXIRA was to be a focal point for information and consultation to be generated from wide-ranging sources, commissioning expert reports where appropriate, to be communicated in a manner accessible to specialists and non-specialists alike. It was to report to the secretary of state for health, in an advisory capacity only, i.e. it was *not* given the statutory powers recommended by the Kennedy report.

In 1998 UKXIRA published its *Guidance on making proposals to conduct xenotransplantation*. Clinical trial applications would be subject to peer review by around six referees appointed by the Authority which would subsequently meet to make its recommendation to Department of Health ministers. Wider involvement in the scrutiny of trial

applications would be provided by the applicant's Local Research Ethics Committee (LREC) on the local suitability of the trial. But, and this is significant in consultative terms, LRECs would only consider an application after it had already been approved by Government. In total, four applications to conduct trials were received by UKXIRA though none were approved (UKXIRA Second Annual Report September 1998-August 1999, London: DH, 2000).

By the beginning of the 2000s, much of the confidence in the scientific progress made throughout the 1990s had completely dissipated. Disappointing pre-clinical trial study results had failed to demonstrate convincing clinical potential. Additionally, Imutran faced a public relations disaster with the leaked report of its lab work by an animal advocacy organisation, *Uncaged Campaigns*.

5.5.4 Discontinuation of UKXIRA

In December 2006, UKXIRA was discontinued with little formal notice, having been in a dormant state for some years. Research ethics committees (RECs) are now the primary authorities responsible for approving trial applications, although their judgements will be subject to approval by the Medicines and Healthcare Regulatory Authority (MHRA), which will be responsible for assessing the risks arising from any such trials. There is, however, little indication that the MHRA will play the same kind of information gathering and awareness raising role of the now disbanded UKXIRA. Both the discontinuation of UKXIRA and the decision to replace it with a new, de-centralised system of regulation were executed without any form of public consultation.

Whilst the UKXIRA model was open to criticism in some notable respects (particularly openness and transparency), Williamson et al (2007) have seriously questioned the adequacy of the new arrangements on the basis that a key instrument of centralised regulation has been abandoned and replaced by a system that fails to take account of the still relevant concerns raised by the Kennedy Report. These authors also comment critically on the independence of RECs, which tend to be overrepresented by those involved in research over lay members, and which will operate without any obligations to seek external specialist help.

5.5.5 Public consultation and overview/summary of socio-cultural dimensions

On the whole, the primary mode of consultation within the UK regulatory order has been overwhelmingly passive in its relationship to public participation and inclusion in policy-making. Almost all consultative processes involve little more than a call for written testimony within a fixed time period targeting interest groups, institutions and known stakeholders.

On the rare occasions when active attempts at consultation regarding xenotransplantation (whether as a central or ancillary issue) have been made, interesting distinctions emerge between events initiated by academics (funded by the Wellcome Trust or the research councils), and those commissioned by government and industry. The former tend to be deliberative studies which allow participants to determine the questions relevant to the assessment of xenotransplantation, for example:

- "Xenotransplantation: risk identities and the human/nonhuman interface" (ESRC funded) – Nik Brown and Mike Michael.
- "Deliberative mapping: a novel analytic-deliberative methodology to support contested science-policy decisions" (Wellcome Trust Funded) - Jacquelin Burgess, Andy Stirling, Judy Clark, Gail Davies, Malcolm Eames, Kristina Staley, Suzanne Williamson.

In contrast, the latter are generally quantitative opinion surveys, for example:

- Market & Opinion Research International (MORI): Public Support for Controversial Technologies Could Increase if Applications are explained. London, UK: Novartis, 1999.
- 2002 UK biotechnology survey (Gaskell et al 2003).

By pre-framing the issue through closed questions, such surveys seem to be geared towards minimising opposition through the construction of an artificial consensus (for a critique of these methods see Hagelin 2004).

Overall, UK policy-making concerning xenotransplantation, as in other areas of the biosciences, is best characterised as a "scientific advisory system" (Frewer and Salter 2002) which has proven relatively impermeable to open up-stream public discussion free of predetermined institutional agendas. Within what we might call the "Westminster model" of science policy-making, public consultation has had an often ambivalent standing. Much of the commentary within policy circles about the standing of "the public" tends to characterise wider public discourse as emotive and insufficiently informed (i.e. a traditional deficit model of public understanding). When instituted by government, a premium tends to be placed on the capacity for participation based on expert-derived knowledge and rationalistic reasoning within an instrumental agenda. Responses that fail to conform to this institutionally sanctioned discourse, particularly "gut reactions" or the much derided "yuck factor", are more usually excluded from debate and discussion. Over the course of decades, formal policy-making in this area has routinely dismissed "citizen vocabularies" that have proven difficult to accommodate within expert authoritative discourse.

5.5.6 Country Chart

Country UK	**1990 - 2000**	**2000-present**
Principle regulatory Authority	Statutory – Secretary of State Advisory – Kennedy (1995); UKXIRA (1997)	UKXIRA terminated (2006) (2006) Clinical trial apps through Central Office or Research Ethics Comms (COREC) then to Medicines and Healthcare Regulatory Authority (MHRA) and Gene Therapy Advisory Committee (GTAC)
Principal policy	Moratoria until 1998 Permitted - UKXIRA guidance on clinical trial applications (1998)	Permitted – through clinical trial route
Public consultations	Kennedy – written representation UKXIRA – written representation and annual meetings (for report only) Eurobarometer	Academic-led: Wellcome Trust funded Deliberative Mapping (DM) Academic-led: Research Council funded focus group research – ESRC (Brown and Michael)
Dominant consultative features	Impermeable: Expert-led advisory committees - Closed meetings – the 'Westminster model' - Little or no evidence of policy-led consultation beyond written submissions to advisory committees. This has tended to the dominant consultative route in the UK Westminster context particularly during the 1990s and early 2000s. Porous: On the question of a range of issues (cloning [Wellcome], biobanks [SATSU], hybrid embryos [DoH]) that has begun to change into the mid 2000s. This is in response to legal changes in 2006 (Legislative and Regulatory Reform Bill) making consultation a requirement where ministers are to table new legislation of amendments to legislation. Although, the character of consultation is left to the discretion of Ministers. Where public consultations have been held – they are explicitly non-binding and not to be treated as a referenda (see hybrid	

Country UK	**1990 - 2000**	**2000-present**
	embryo debate). Permeable: Academic-led – little influence - poorly embedded in policy-making	
Key cultural features	Relatively polarised: Strong institutionalisation of both scientific and animal advocacy positions with Government firmly backing the former. Strong cultural history of animal advocacy bodies and organisations.	

5.5.7 References

Bloomfield, D., Collins, K., Fry, C. and Munton, R. (2001) Deliberation and Inclusion: Vehicles for Increasing Trust in UK Public Governance*? Environment and Planning C: Government and Policy* 19(4): 501–13.

Brown N. Xenotransplantation: normalising disgust. *Science as Culture*, 1999; 8: 327–355.

Brown, N. Faulkner, A., Kent, J., Michael, M. (2006) Regulating Hybrids - 'making a mess' and 'cleaning up' in Tissue Engineering and Xenotransplantation, *Social Theory and Health*, 4, 1. 1-24

Burgess, J., Stirling, A., Clark, J., Davies, G., Eames, M. and Staley, K. (2007) Deliberative Mapping: a novel analytic-deliberative methodology to support contested science-policy decisions, *Public Understanding of Science*, 16, 299-322

Cabinet Office and Office of Science and Technology (1999), *The Advisory and regulatory Framework for Biotechnology: Report from the Government's Review* (Stationery Office, London).

Department of Health (1997) *Animal tissue into humans: a report by the Advisory group on the Ethics of Xenotransplantation,* London: HMSO

Frewer, L and Salter, B. (2002) Public attitudes, scientific advice and the politics of regulatory policy: the case of BSE, *Science and Public Policy*, 29, 2, 137-145

Gaskell, G., Allum, N., Bauer, M., Jackson, J., Howard, S. and Lindsey, N. (2003) Climate change for biotechnology? UK Public opinion 1991-2002, *AgBioForum*, 6 (1&2), 55-67

Hagelin, J. (2004) Public opinion surveys about xenotransplantation, *Xenotransplantation*, 11, 551-558

Her Majesty's Government (2001), *The Interim Response to the Report of the BSE Inquiry by HM Government in Consultation with the Devolved Administrations* (The Stationery Office, London).

Michael, M. and Brown, N. (2004) The Meat of the Matter: Grasping and judging in xenotransplantation, *Public Understanding of Science*, 13, 379-397

OST - Guidelines 2000: *Scientific Advice and Policy Making and issued a draft Code of Practice for Scientific Advisory Committees*

Stirling, A. (2005) Opening Up or Closing Down: Analysis, Participation and Power in Social Appraisals of Technology, in M. Leach, I. Scoones and B. Wynne (eds) *Science and Citizens: Globalisation and the Challenge of Engagement*. London: Zed Books.

Wellcome Trust (1998) *Public Perspectives on Human Cloning. Input to Human Genetics Advisory Committee and the Human Fertilisation and Embryology Authority's consultation document, Cloning Issues in Reproduction, Science and Medicine.* URL: http://www.wellcome.ac.uk/en/1/awtpubrepcln.html

Williamson, L., Fox, M. and McLean, S. (2007) The Regulation of Xenotransplantation in the United Kingdom after UKXIRA: Legal and Ethical Issues, *Journal of Law and Society* 34 (4), 441-64.

Wilsdon, J. and Willis, R. (2004) *See-through Science: Why Public Engagement Needs to Move Upstream*. London: Demos.

Yearley, S. (2001) Mapping and Interpreting Societal Responses to Genetically Modified Crops and Food, *Social Studies of Science* 31(1): 151–60.

5.6 Non-European comparator countries: Canada, Japan and the US

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5.6.1 Canada

5.6.1.1 Introduction and Methods

This document summarizes the formal introduction of public consultation to xenotransplantation (XTP) policy-making in Canada. Canada's public consultation on XTP was a permeable process — the government actively sought to engage in inclusive and open discussion on this policy issue. The consultations were also considered a significant and positive governmental effort since it was the first time that Health Canada had carried out such an extensive deliberative consultation.[88] Yet, it is suggested that such public participation approaches remain experimental rather than becoming systematic, institutionalized or sustainable.

This paper is based on the evaluation of electronic and written documents that have informed the policy-making process of XTP in Canada and on accounts of activities appearing in various policy reports. These documents are either produced by the Canadian government (conference and workshop reports and summaries, meeting minutes and notices to hospitals and industry), or are publications, commentaries and evaluations by third parties, the private sector or academia. When conference proceedings and planning meetings are presented, particular attention was paid to the nature of the organizational interest and expertise (broad or narrow) of those invited. The goals and results of each event are summarized with the intention of providing a clear timeline and presenting inherent features of the Canadian policy-making process.

5.6.1.2 Overview of landmark developments and timeline – Key features of policy-making and process

In November 1997, at the recommendation of its expert working group on organ and tissue transplantation, Health Canada sponsored the National Forum on Xenotransplantation: Clinical, Ethical and Regulatory Issues. The expressed purpose of this forum was to discuss the risks, benefits, ethics, regulatory issues, research and information requirements for the issue of xenotransplantation.[89] At its conclusion a central theme prevailed: the need for public consultation at all stages of decision-making. To this end, in April 2000, the TPP held a Planning Workshop to consult formal stakeholders on the nature of and process for public

[88] E.F. Einsiedel. Assessing a controversial medical technology: Canadian public consultations on xenotransplantation. *Public Understanding of Science.* 2002(11): 327.
[89] Health Canada, "Report of the National Forum on Xenotransplantation Clinical, Ethical and Regulatory Issues." (Ottawa: Therapeutic Products Programme, November 6 - 8, 1997). p. 2.

participation in the XTP debate. Upon receiving the suggestions of this Planning Workshop, Health Canada hired a third party, the Canadian Public Health Association (CPHA), to organize the process and who in turn hired a Public Advisory Group (PAG) to conduct the actual consultations.

In 1999, a year prior to the public consultation process, Health Canada's Expert Working Group on Xenotransplantation Standards released for public comment the draft Proposed Canadian Standard for Xenotransplantation.[90] The Standard was written by fourteen clinical, ethical, scientific and regulatory health specialists and participants of the National Forum on Xenotransplantation in 1997 and meant to become the criterion for clinical trials and regulation of XTP in Canada. It was also considered a dynamic document intended to respond in a timely fashion to current scientific knowledge and ethical principles.[91]

Each of the six regional forums for the public consultation consisted of 15 to 25 lay citizens who met and deliberated on the question, "Should Canada proceed with xenotransplantation and if so, under what conditions?" In January 2002 seven recommendations were formally presented to the Minister of Health, the first being "That Canada should not proceed with xenotransplantation involving humans at this time [clinical trials], as there are critical issues that first need to be resolved."[92]

In the absence of requests to proceed to clinical trials, and the exhaustive permission requirements needed in order to apply,[93] it appears that the Canadian government is honoring the wishes of its citizens by not proceeding with XTP until critical issues have been further explored. Health Canada has initiated an update to this Standard[94] although the delay in the update of this document could also be interpreted as a de facto moratorium.

5.6.1.3 Public consultation – and overview/summary of socio-cultural dimensions

The measured approach of the Canadian government to the XTP issue is harmonious with the accepted socio-cultural dimensions of Canada. In other examples of contentious issues, Canadian approaches lack the highly polarized views seen in other countries. The Canadian socio-political context has consistently been defined as the middle ground: it is where the cultural influences emanating from Europe (particularly the UK) and the U.S. find a confluence. Canada's so-called "Westminster-style parliamentary system" has been

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[90] Health Canada, *Xenotransplantation – Biotechnology – Science and Research*. Retrieved June 3, 2009. < http://www.hc-sc.gc.ca/sr-sr/biotech/about-apropos/xeno-eng.php>
[91] Health Canada, i.
[9292] Canadian Public Health Association. *Animal-to-human transplantation: Should Canada proceed? A Public Consultation on Xenotransplantation* (Ottawa: Canadian Public Health Association, 2001) <http://www.xeno.cpha.ca/english/finalrep/reporte.pdf> p. 3
[93] In order for a trial to be approved, both the clinical trial and the medical device must be authorized. These requirements are subject to various regulations of the Food and Drug Act and Medical Devices Regulations under Health Canada.
[94] Health Canada, *Xenotransplantation – Biotechnology – Science and Research*. Retrieved June 3, 2009. < http://www.hc-sc.gc.ca/sr-sr/biotech/about-apropos/xeno-eng.php>

described as leading to the fostering of a more powerful bureaucracy.[95] At the same time, the physical proximity to the U.S. has often led to an identity formation frequently defined in opposition to its next-door neighbor. In terms of regulatory style, in contrast to the more adversarial culture in the U.S., policy-making in Canada has tended towards more collaborative efforts. Where U.S. advocacy groups have thus tended to rely importantly on the judicial system, a more consensual approach tends to be pursued in Canada.

How do these influences – sometimes operating in tension – express themselves where public consultation is concerned? On one hand, there has been a move in the last decade and a half to pursue more collaborative forms of policy-making. This has been expressed through greater uses of multi-stakeholder consultations and mini-experiments with forms of public engagement. On the other hand, the reliance on expertise remains strong among policy elites, so much so that the latter efforts at democratizing policy making can be characterized as experimental, unsystematic, and muddling through.

The public consultation on xenotransplantation can be viewed as an innovative experiment for several reasons:[96] first, it was an arms-length process rather than an in-house operation. Second, implementing a citizen jury approach was risky as the results were unpredictable and the formulation of a specific question ("Should Canada proceed to clinical trials?") rather than employment of a more general framework (for example, identifying key issue-areas for the technology) made this process even riskier.

[95] Lipset, SM. *Revolution and counter-revolution: change and persistence in social structures*. Chicago: Univ of Chicago press. 1990; Vogel, David M. *National Style of Regulation*. Cornell University Press, Ithaca, NY. 1986.
[96] On the other hand, two factors left little room for the ministry to do otherwise. Its own expert committee pushed for such a consultation to take place, and the ministry had already suffered from a major crisis in confidence from its (botched) oversight of a controversy over tainted blood (i.e.,blood available in the blood banks had not been fully tested despite indications that supplies had been contaminated by HIV-positive and Hepatitis C donors, resulting in a number of infections in its wake).

5.6.1.4 Country Chart

Country - Canada	**1990-2000**	**2000-present**
Principal Regulatory Authority	Statutory: Health Canada Advisory: Therapeutic Products Programme (TPP)	Statutory: Health Canada Advisory: Two directorates of the Health Products and Food Branch (HPFB): the Biologics and Genetic Therapies Directorate (BGTD) and the Therapeutic Products Directorate (TPD)
Principal Regulatory Policy	1997 (November): The National Forum on Xenotransplantation 1999 (February): Notice to Interested Parties: Intent to Develop a Regulatory Framework for Xenografts. 1999 (March): Notice to Hospitals: Clinical Use of Animal Cells, Tissues, or Organs to Treat Patients. 1999 (July): Expert Working Group on Xenotransplantation draft Proposed Canadian Standard for Xenotransplantation, Health Canada, Ottawa.	Xenotransplantation is not prohibited, yet no clinical trial application has yet been received or approved by Health Canada.
Public Consultations	1999 (March): Therapeutic Products Programme (TPP) telephone Public Opinion Survey 2000 (April): TPP's Planning Workshop: Public Involvement for Xenotransplantation. Health Canada hires a third party, the Canadian Public Health Association (CPHA) to conduct a public involvement plan. The CPHA forms a Public Advisory Group to conduct the public consultation.	2001 (March-July): Public Consultation Animal-to-Human Transplantation: Should Canada Proceed? 2001 (December): Canadian Public Health Association. Animal-to-human transplantation: Should Canada proceed? A Public Consultation on Xenotransplantation.[3]

Country - Canada	**1990-2000**	**2000-present**
Dominant Consultative Features	Porous: Health Canada has identified the need to update the Draft Standard for Canada and will do further analysis with consideration of the public consultation. Permeable: Government-led Public Consultation (2000-2001): Animal-to-Human Transplantation: Should Canada Proceed? 1. Health Canada initiated an arms-length consultation through a non-government organization. 2. The process was separate from its expert consultation process, providing an opportunity for public views to emerge independently. 3. The process accommodated two features of the Canadian socio-political landscape: its strong regional character and a recognition of its aboriginal population. 4. The consultation broadly defined "expert" knowledge including input from a range of interests, experience, ethical perspectives and scientific expertise. 5. The public consultation was a dialogic process marking an intersection of expert and lay knowledges. 6. The government actively sought to engage in inclusive and open discussion on this policy issue.	
Key Cultural Features	• Canada has a moderate approach to biotech issues such as genetically modified food. • Stakeholder groups for animals are more likely to have animal welfare leaning rather than be animal rights advocates. • The abortion issue also similarly reflects a more moderate stance, without the highly polarized debates often characterizing U.S. positions.	

5.6.1.5 References

"VII.7. Food Biotechnology: Politics and Policy Implications." Cambridge World History of Food. Cambridge: Cambridge University Press, 2000. Credo Reference. 31 July 2009

<http://www.credoreference.com.ezproxy.lib.ucalgary.ca/entry/cupfood/vii_7_food_biotechnology_politics_and_policy_implications>

Canada Gazette, Government Notices. (Department of Health, Food and Drugs Act, Vol. 133, No. 6 — February 6, 1999). Retrieved July 31, 2009. <http://www.gazette.gc.ca/archives/p1/1999/1999-02-06/html/notice-avis-eng.html#i4>

Canadian Public Health Association. "Animal-to-human transplantation: Should Canada proceed? A Public Consultation on Xenotransplantation." (Ottawa: Canadian Public Health Association, 2001) <http://www.xeno.cpha.ca/english/finalrep/reporte.pdf>

Creasey, David. P. "Is Anyone Listening? The perspective of policy makers on public participation in policy making on Xenotransplantation in Canada and the United States." Unpublished MA Thesis, University of Calgary, Alberta. 2003.

Eaton, Emily, "Getting Behind the Grain: The Politics of Genetic Modification on the Canadian Prairies." Antipode 41(2): 256-281.

Einsiedel, Edna, F. "Assessing a controversial medical technology: Canadian public consultations on xenotransplantation." Public Understanding of Science. 2002(11): 317-318.

Einsiedel, Edna, F. & Ross, Heather. "Animal Spare Parts? A Canadian Public Consultation on Xenotransplantation." Public Understanding of Science. 2002. 8(4): 579-591.

Health Canada, "Proposed Canadian Standard for Xenotransplantation" (Draft #14) by Andre La Prairie (Ottawa: Therapeutic Products Programme, July 1999).

Health Canada, "Report of the National Forum on Xenotransplantation Clinical, Ethical and Regulatory Issues." (Ottawa: Therapeutic Products Programme, November 6 - 8, 1997). <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/brgtherap/forum_rep-rap_xeno-eng.pdf>

Health Canada, "Report from the Planning Workshop: Public Involvement for Xenotransplantation." (Ottawa: Therapeutic Products Programme, April 10-11, 2000). <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/brgtherap/awsreport-rapportvif-eng.pdf>

Health Canada. "Revised Fact Sheet on Xenotransplantation." (Ottawa). Accessed June 3, 2009. <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/brgtherap/xeno_fact-fait-eng.pdf>

Health Canada, "Viewpoint: A Summary of Recommendations from the National Forum on Xenotransplantation." (Ottawa: Therapeutic Products Programme, March 1999, Revised: July 1999). <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/brgtherap/forum_summary-resume-eng.pdf>

Health Canada, “Xenotransplantation – Biotechnology – Science and Research.” Retrieved June 3, 2009. < http://www.hc-sc.gc.ca/sr-sr/biotech/about-apropos/xeno-eng.php>

Industry Canada, “Meech Lake Planning Meeting: Ethics, Science & Governance.” (Ottawa: June 13, 14, 15 1999).

Kishchuk, Natalie. “An Evaluation of the Public Consultation on Xenotransplantation. Evaluation Report to the Canadian Public Health Association.” Ottawa: 2002.

Lipset, SM. “Revolution and counter-revolution: change and persistence in social structures.” Chicago: Univ of Chicago press. 1990.

McLean, S.A.M. & Williamson, L. “A Review of National and International Responses to Xenotransplantation.’ In: Xenotransplantation: Law and Ethics. Ashgate Publishing Limited. 2005: 141-145.

Medlock, Jennifer. “What’s the Verdict? Evaluating a citizens’ jury on xenotransplantation.” Unpublished Master’s Thesis, University of Calgary. Alberta. 2001.

Mortensen, Melanie, J. “In the Shadow of Doctor Moreau: A Contextual Reading of the Proposed Canadian Standard for Xenotransplantation.” University of Ottawa Law and Technology Journal, 2005: 37-74.

Organisation for Economic Co-operation and Development, “Regulatory

Developments in Xenotransplantation in Canada.” Retrieved June 3, 2009, from

<http://www.oecd.org/document/0/0,3343,en_33873108_33873277_1886912_1_1_1_1,00.html>

Public Health Agency of Canada (PHAC), “Report of the Xenotransplantation Surveillance Workshop - CCDR Volume 27S1 July 2001.” Retrieved July 2, 2009. <http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/01vol27/27s1/27s1b_e.html>

Public Advisory Group on Xenotransplantation, Letter to the Honourable Allan Rock, Minister of Health, January 7, 2002 from Dr. Heather Ross and Mr. Robert Van Tongerloo, Co-Chairs.

The Islet Foundation, “Xenotransplantation: Ethics, Science & Governance, Meech Lake, Quebec, Canada, June 13-15 1999” by Alastair Gordon. Retrieved July 31, 2009. <http://islet.org/47.htm>

Vogel, David M. “National Style of Regulation.” Cornell University Press, Ithaca, NY. 1986.

5.6.2 Japan

5.6.2.1 Introduction and Methods

This summary is based on English language documents identified by web and literature searches describing the current state of public participation, policy-making and socio-cultural dimensions on transplantation and xenotransplantation in Japan.

Very few donors are available for human to human transplantation in Japan. Fears of premature organ transplants using brain-based criteria to define death are pertinent.[97] In 1994 a bill to legalize the pronouncement of brain death was presented to the Diet (an elected House of Representatives and House of Councillors) and was made law in 1997. Still, between 1997 and 2002 only 15 transplants were conducted from those defined under the bill as potential donors (Sato et al, 2006).

Although Japan’s policy-making process may be categorized as an impermeable one - law-making in Japan is traditionally in the hands of professionals, government appointed academics and bureaucrats - due to political and public health scandals over the past 40 years, an opportunity for more public participation is suggested for the future.

5.6.2.2 Overview of landmark developments and timeline – Key features of policy-making & process

Two events suggest the current state of xenotransplantation policy in Japan: the first is the meeting of the International Xenotransplantation Association held in Japan in 1999, and the second is the Biocult public opinion survey run under the Eurobarometer in 1996 and reviewed by Macer et al. in 2002.

Japan hosted the 5th Meeting of the International Xenotransplantation Association in 1999. Low organ donation rates prompted Hiroshi Takagi, director of the JR Tokai General Hospital to comment "it may take another decade before the practice of organ transplants becomes accepted" and "Japan should pursue research on alternatives like xenografts more aggressively" (Triendl, 1999). At this time the Japanese Ministry of Health and Welfare

[97] The dominant case used to introduce the unease with allotransplantation in Japan is the first heart transplant in 1968. The donor was a drowning victim for whom brain death had not been officially established (Sato et al. 2006) prompting “serious questions about the extent of the medical treatment given to [the victim of] drowning” (Kimura, 1998, 55). Concerns of conflict of interest and “the idea of beloved brain-dead members of their family being cut up as donors, even when the heart was still beating and the body still warm” were appalling to many Japanese (Deguchi, 1999). Fears of premature organ transplants using brain-based criteria to define death remain pertinent. Consequently the legalization of allotransplantation only occurred in 1997 and the first legal heart transplant in 1999. Michael Brannigan (1999), suggests that because the surgeon and his team made no official apology, the public was given the impression that the team was “not willing to assume accountability for breaching the public trust” that the “incident did much to intensify public distrust of the medical profession” (Brannigan, 1999, 290).

(MHW) had a plan for a regulatory framework for xenotransplantation studies compatible with regulatory approaches proposed in Europe and the US, yet Kikuo Nomoto, a professor in the Department of Immunology at the University of Kyushu, argued that it was simply too early to push ahead with xenotransplanation: "We have to overcome the mental barriers towards organ transplants in this country before we can deal with any other issue"" (Triendl, 1999).

While regulators have debated the status of xenotransplantation, academics have sought out public opinion. Macer et al. (2002) compared telephone (1997) and mail-out surveys (1999-2000) based on the European Eurobarometer (1997). The authors focused on xenotransplantation. Respondents included four groups, the Japanese public, high school and university students, and scientists. Macer et al. show that the results of the surveys are similar to Western countries in willingness to donate organs (p. 360), but that Japan has the greatest gap between those who say they will donate organs and those who actually do (p. 360). The concept that Japanese people have a special cultural barrier to donations from brain-dead bodies “has been dismissed by Japanese sociologists and religious groups” (p. 360) - yet Macer et al. add that the Japanese have less trust in medical doctors than people in New Zealand, Australia or the UK (p. 360) which may provide a reason for their doubt in organ transplantation. Macer et al. suggest this distrust in the Japanese medical system may also be due to lack of “effective doctor-patient communication and the idea of informed consent” (p. 360).

The original and controversial transplant case in 1968 did much to increase the public distrust of the medical system (Brannigan, 1999). Nadoka Nakamura (2006) also suggests that various bureaucratic scandals in the 1990s, including an underestimation of the risk of BSE, and the failure of the Ministry of Health and Welfare to disallow unheated blood products (p. 63) and protect hemophiliac patients from HIV, also engendered a distrust in the Japanese political and medical system. These scandals in part led administrative reforms in January 2001 (p. 63). Prime Minister Koizumi’s first general policy speech in 2001 announced that he would advance “active and honest dialogues with the public, and had a mission to restore public confidence and trustworthiness of politics” (p. 72). Since 2001, prudent models of public participation have been applied, although no mention is made by Nakamura to the topic of xenotransplantation.

5.6.2.3 Public consultation – and overview/summary of socio-cultural dimensions

Akira Deguchi’s article, *Organ transplantation, identity, and the imagined community*, (1999) explores cultural approaches to identity and transplanted tissues and organs in Japan. Deguchi begins by introducing Anpanman, a superhero with a bean-jam gum sponge-head that is regularly compromised by his opponents. Anpanman is always saved by his comrades who throw him another head. Deguchi suggests that this character played a part in spreading the idea of transplantation as it aired at the same time as the brain death

debate. Despite all his new heads Anpanman keeps his identity. Deguchi finds this a puzzling concept because if the head is the locus of personality, how is Anpanman retaining his personal identity? He explains this in part through the Japanese folklorist tradition. In real-life pre-capitalist Japan, babies' souls "were thought to be unstable, easily detaching from their bodies" (p. 121). Customs and ceremonies were therefore developed to encourage a connection between body and soul in a person's early life (Deguchi, 2002). Deguchi argues that the concept of body and mind is a dualism found in traditional Japanese culture and that the concept of transplantation is not a novel, but a familiar concept to the Japanese public.

Deguchi writes that considering body parts as "gifts" could cause a "personal identity crisis in the public imagination" (p. 122). Ideas of xenotransplantation in popular culture are debated in the Japanese horror novel, Ninju Zaiku (Deguchi, 1999). The main character is partially made of pig body parts. She wonders if she is "truly a human being or a pig" (p. 122). Her friend suggests that the pig parts are only commodities and that she "has continuity and integrity in herself" (p. 122). This dichotomy of transplanted body parts as "inalienable gifts" versus "alienable commodities" is reflected in the nation state's approach to body parts—the nation expects body parts to be donated to unknown strangers voluntarily, but within the "imagined community" they are commodities. The conversion of impressions of a loved one's body from 'gift' to 'commodity' is a difficult one. Deguchi concludes that the problem is not one of differences in cultural identity as suggested between Japan and Western countries, but one of "the world of modernity" (p. 124) where "no individual can be someone else at the same time as oneself" (p. 125). In the case of "pig-ness" (p. 128) it is best if the organ is no longer identified as "pig."

5.6.2.4 Country Chart

Country Japan	**1990-2000**	**2000-present**
Principle Regulatory Authority	Ministry of Health and Welfare	
Principle Regulatory Policy	Permitted - Trials that are not new pharmaceutical products are not subject to oversight by the Health Ministry. As of 1999 there are no guidelines nor mechanism to monitor clinical trials (Triendl, 1999)	

Country Japan	**1990-2000**	**2000-present**
Public Consultations	EU 1996 – Biocult survey and young citizens 11-18 yr olds expanded to Japan and New Zealand. Academic: Public opinion survey 1997 & 2000 by Macer et al., (2002). There is no mention of other public consultation on xenotransplantation in Japan (in the English literature)	
Dominant Consultative Features	Impermeable: The traditional making of laws in Japan is in the hands of professionals, government appointed academics and bureaucrats.	
Key Cultural Features	The brain-based death criteria debate has dominated transplantation debate. After the bill to legalize the declaration of brain death (1997), human to human organ transplantation has been allowed when both the donor has given written consent to the determination of brain death *and* to organ transplant. The use of brain death criteria can still be refused by the family (Sato et al. 2006). Outside of some government involvement and research interests, no other stakeholders have been found to have raised the issue of xenotransplantation. i.e. Animal rights groups and welfare groups are not visible, and neither are patient groups on the topic of xenotransplantation.	

5.6.2.5 References

Arie, F. (2008). Ethical Issues of Transplant Coordinators in Japan and the UK. *Nursing Ethics*, 15(5), 656-659.

Bagheri, A. (2003). Criticism of “Brain Death” Policy in Japan. *Kennedy Institute of Ethics Journal*, 13(4), 359–372.

Brannigan, M.C. (1999). Relationality and Consensus in Japan: Implications for Bioethics Policy. *Health Care Analysis* 7, 289–296.

Deguchi, A. (1999). Organ transplantation, identity, and the imagined community. *Journal of the Anthropological Society of Oxford*. 30(2), 119-130.

Hagelin J. (2004). Public opinion surveys about xenotransplantation. *Xenotransplantation*, 11, 551–558.

Kimura, Rihito. (1998). Organ Transplantation and Brain-Death in Japan. *Annals of Transplantation*, 3(3), 55-58.

Nakamura, Madoka. (2006). The Changing Policy Environment in Japan. In: *The work of policy: an international survey*, Hal K. Colebatch, Ed. Lexington Books. 61-82.

Macer, D., Inaba, M., Maekawa, F., Chen Ng, M. and Obata, H. (2002). Japanese Attitudes Toward Xenotransplantation. *Public Understanding of Science*, 11, 347–62.

Sato, H., Akabayashi A., & Kai, I. (2006). Public, Experts, and Acceptance of Advanced Medical Technologies: The Case of Organ Transplant and Gene Therapy in Japan. *Health Care Anal*, 14, 203–214.

Triendl, R. (1999). Japan hosts its first xenotransplantation conference. *Nature Medicine* 5, 1335. Retrieved Oct. 23, 2009. http://www.nature.com.ezproxy.lib.ucalgary.ca/nm/journal/v5/n12/full/nm1299_1335.html

Zieler, K. (2009). Deadly pluralism? Why death-concept, death-definition, death-criterion and death-test pluralism should be allowed, even though it creates some problems. Bioethics, 23(8), 450-459

5.6.3 The US

5.6.3.1 Introduction and Methods

This summary is based on English language documents identified by web and literature searches, as well as interview material from the principal US regulatory authority for xenotransplantation, the Food and Drug Administration (FDA).

The US has been a leader in the science of xenotransplantation since the 1960s. In 1984, California was the site of a significant event for xenotransplantation science: the first transplant into an infant of a baboon heart. The case of Baby Fae was both famous and controversial – not only because the child lived less than a month post transplant, but also as there were indications of ethical transgression in her surgeon's decision to transplant from a baboon rather than wait for a suitable human donor (Spillman and Sade 2007). The controversy surrounding this rather extreme example of cross-species transplants did not prevent US science from conducting further explorations, and clinical trials (particularly using transgenic pigs) continued into the 1990s. While the US retains a relatively permissive stance towards xenotransplantation clinical trials, this is only the result of considerable deliberation in the 1990s arising from scientific evidence on two key areas of scientific uncertainty: viruses and rejection.

5.6.3.2 Overview of landmark developments and timeline – Key features of policy-making & process

As in many nations where xenotransplantation is on the policy agenda, the 1990s was the key decade for regulatory development. Years of joint effort involving several[98] Public Health Service (PHS) agencies resulted in *Guidelines on Infectious Disease Issues in Xenotransplantation* (1996). Following this, Robin Weiss published a groundbreaking 1997 *Nature Medicine* paper which reported research findings indicating porcine endogenous retrovirus (PERV) cells could infect humans (Patience, Takeuchi and Weiss 1997). This paper had a great effect on how scientists viewed the viability of xenotransplantation clinical trials. At the same time, FDA researchers were conducting similar studies (published the following year – Wilson et al., 1998) and had been working to establish regulatory guidelines to address the uncertainties of this experimental research. n late 1998 the FDA called a halt[99] to existing clinical trials and demanded that three conditions be met in order for trials to be continue: briefly a) researchers must provide assays to demonstrate they had screened source animals for PERVs; b) trials must use a method (usually assays or serology) to monitor study subjects for evidence of infection; and c) studies must provide revised

[98] Namely, the Department of Health and Human Services, the Centers for Disease Control and Prevention, the FDA, Health Resources and Services Administration, National Insitutes of Health, and the Office of the Assistant Secretary for Planning and Evaluation (Creasey 2003, 59).
[99] Although this is described in some coverage as a moratorium (see Creasey 2003), the FDA is clear that it was instead the institution of further approval criteria – which resulted in a temporary hiatus for existing trials.

informed consent sheets to clearly reflect that there was still considerable uncertainty around the risk of virus transmission. After five months, trials meeting these criteria resumed, and they remain a stipulation for xenotransplantation trials today.

Rejection and infection continue to be topics of scientific uncertainty and have, it has been suggested by FDA representatives, contributed to the dearth of activity in the science (with the knock-on effect of reducing the need for excessive regulatory attention). However, advances in the use of pig islet cells to treat diabetes may have sufficient potential to reawaken interest in xenotransplantation both in terms of science and regulation. This area continues to be governed in the US by the *Public Health Service Act* of 1944 and the *Federal Food, Drug and Cosmetic Act* of 1938, bolstered by more recent guidance documents as part of what the FDA refers to as its Xenotransplantation Action Plan. This guidance includes the PHS Guidelines mentioned above along with guidance documents for industry (Bloom 2007). The FDA's Center for Biologics Evaluation and Research, Division of Cellular and Gene Therapies is primarily responsible for regulatory oversight in xenotransplantation, and consults internationally in this area with, e.g., the World Health Organization and the Council of Europe.

5.6.3.3 Public consultation – and overview/summary of socio-cultural dimensions

Public consultation is routinized within FDA policy development. Several factors may be identified as contributing to this consultative character.

The size and complexity of the US administration governing health technologies may seem unusual in a decentralized federalist system like the US, which is also well-known for its resistance to adopting a socialized medicine model. However, the US also has a history of instituting scientific advance as a national priority, particularly in relation to military applications. The model of scientific autonomy – "exceptionalism" – championed by the wartime head of the US Office of Scientific Research and Development, Vannevar Bush, generated a pervasive discourse capable of overrunning more participative/democratic approaches to governing science and technology (Hess 2006, 123). The policy of scientific autonomy facilitating American military science has, since the Second World War, had a concurrent effect on driving support for research and development in other fields – including health – with as little regulatory limitation as possible.

In the face of this lightly-fettered scientific change and growth, the implications of rapid technological development began to come more to the fore. In 1972, the US Congress passed the Technology Assessment Act which established the Office of Technology Assessment (OTA) to explore the consequences of technology for the purposes of policy development (U.S. Congress 1972). Part of its mandate was to conduct detailed impact analyses in a structure of accountability to both government and the public (O'Brien and Marchand 1982). In addition, the 1970s saw a well-known demonstration of strong

democracy in technology governance, in the form of the Asilomar town hall meetings associated with the moratorium on recombinant DNA technology (Krimsky 1982). Although the OTA was dismantled in 1995, it played an important role in the cultural shift to bring broader publics into decision-making processes regarding science and technology.

Specific to xenotransplantation, in 1999 the US Department of Health and Human Services established the now-defunct Secretary's Advisory Committee on Xenotransplantation (SACX) which had a majority membership of scientists, but also included patient and animal advocates. SACX meetings were open to the public for comment (Creasey 2003). In recent years the lack of activity and interest in xenotransplantation has obviated the need for the Committee, and therefore any remaining issues associated with the technology are now dealt with through the FDA.

Perhaps most significantly for the FDA, the role of HIV patient groups in lobbying for a stronger voice in therapeutic regulation (Epstein 1996) played an extremely important role in initiating a cultural shift within the regulatory body. Currently the first step in the FDA's standard operating procedure for good guidance practice is to hold an open public meeting; it is, therefore, a routine part of policy practice. Since the mid-1990s, the FDA Office of Special Health Issues has coordinated a Patient Representative program whereby well-informed members of the public can be vetted and granted special status to participate in FDA Advisory Committees, which may view confidential information in the process of policy development (FDA 2009). FDA Advisory Committees meet regularly and address a range of issues. At this writing, xenotransplantation has been a somewhat dormant issue of late. However, the matter of clinical trial disclosure is under discussion at the FDA[100] and may be an issue for future Advisory Committee deliberation.

5.6.3.4 Country Chart

Country United States	**1990-2000**	**2000-present**
Principle Regulatory Authority	FDA/PHS	FDA/PHS
Principle Regulatory Policy	Permitted; de facto 5-month moratorium in 1998/1999 put existing policies on hold until clinical trial researchers could meet three conditions.	Permitted

[100] Two key issues in these discussions may be a) that the FDA has required disclosure of conflict of interest for investigators on clinical trials since 1999 – but there have been suggestions this requirement is being ignored (see Washington Post 2009), and b) the recent passage by Congress of the requirement that post Phase II clinical trials be registered on the government database.

Country United States	**1990-2000**	**2000-present**
Public Consultations	Frequent; through FDA advisory committees and through SACX	SACX defunct; FDA Advisory Committees continue to meet regularly and address xenotransplantation issues as they arise.
Dominant Consultative Features	Semi-permeable: while it relies on expert scientific advice and protects industrial intellectual property, it also has a well-developed consultative culture connected to a tradition of technology assessment.	
Key Cultural Features	Pro-innovation, pro-science; decentralized regulatory style; on balance less political pressure from animal rights bodies, more from pharmaceutical/biotech industry.	

5.6.3.5 References

---. Health highlights, Jan. 13 2009. *Washington Post*. Available at: http://www.washingtonpost.com/wp-dyn/content/article/2009/01/13/AR2009011301528_2.html [Accessed November 23, 2009].

Bloom, E.T. (2007). National policies for xenotransplantation in the USA. *Xenotransplantation*, 14: 345-346.

Creasey, D. *Is anyone listening? The perspective of policy makers on public participation in policy making on xenotransplantation in Canada and the United States*. Unpublished Master thesis, University of Calgary, 2003.

Epstein, S. (1996). *Impure Science: AIDS, activism, and the politics of knowledge*. Berkeley: University of California Press.

Food and Drug Administration (FDA). Xenotransplantation. Available at: http://www.fda.gov/BiologicsBloodVaccines/Xenotransplantation/default.htm [Accessed November 23, 2009.]

Food and Drug Administration (FDA). Patient Representative Program. Available at: http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/PatientInvolvement/ucm123858.htm [Accessed November 23, 2009.]

Hess, D.J. (2006). Antiangiogenesis research and the dynamics of scientific fields: Historical and institutional perspectives in the sociology of science. In: S. Frickel and K. Moore, eds., *The New Political Sociology of Science*, 122-147. Madison: University of Wisconsin Press.

Krimsky, S. (1982). *Genetic Alchemy: The social history of the recombinant DNA controversy*. Cambridge, Massachussetts: MIT Press.

O'Brien, D.M. and Marchand, D.A. (1982). The politics of technology assessment: Institutions, processes, and policy disputes. Toronto: Lexington.

Patience, C., Takeuchi, Y, and Weiss, R. (1997). Infection of human cells by an endogenous retrovirus of pigs. *Nature Medicine*, 3, 282-286.

Spillman, M.A. and Sade, R.M. (2007). Clinical trials of xenotransplantation: Waiver of the right to withdraw from a clinical trial should be required. *Journal of Law, Medicine and Ethics*, 35(2): 265-272.

U.S. Congress (1972). The Technology Assessment Act of 1972. Public Law 92-484. 92nd Congress, H.R. 10243. Available at: http://govinfo.library.unt.edu/ota/Ota_5/DATA/1972/9604.PDF [Accessed November 23, 2009.]

Wallis, C. (1984). Baby Fae stuns the world. *Time*, November 12. Available at: http://www.time.com/time/magazine/article/0,9171,926947,00.html [Accessed November 23, 2009].

Wilson, C., Fishman, J.A. and Sykes, M. (2008). Tribute to Eda T. Bloom, PhD. *Xenotransplantation*, 15: 69-71.

Wilson, C.A., Wong, S., Muller, J., Davidson, C.E., Rose, T.M. and Burd, P. (1998). Type C retrovirus released from porcine primary peripheral blood mononuclear cells infects human cells. *Journal of Virology*, 72(4): 3082-3087.

5.7 Public view on biotechnology in Eurobarometer Special Surveys

Agnes Allansdottir

5.7.1 Introduction

This chapter is an attempt to tease out some selected features of public views on biotechnology in Europe in general, and in the countries participating in the CIT-PART project in particular, in light of the project objective of exploring how citizens' views and voices are heard or ignored in policy making processes. This version is intended as a background paper, geared more towards raising interesting questions for further analysis than to giving definitive answers to any given sets of questions. That is to say, these pages are intended to serve as input for new insights for the case studies to be conducted within the project.

In an attempt to capture and to monitor the views of the European public towards developments in the life sciences the European Commission has funded a regular series of Eurobarometer Special Surveys since the early nineties. The rationale for these surveys was the recognition by the European authorities that, as well as constituting a promising technology for the future, biotechnology has the potential to generate public concerns. This illustrates a remarkable sensitivity towards public concerns and sentiments on behalf of the European Commission that has persisted over time. The primary aim of this series of surveys is to provide a source of sound social scientific input and advice to policy making processes dealing with the life sciences in Europe. The collective efforts that have gone into designing, collecting and analysing these surveys have generated an impressive amount of precious and high quality research material on how European societies have confronted the hopes and challenges raised by advances in biotechnology over the years.

This paper draws upon certain aspects of this dataset in order to explore public views on medical biotechnology with a particular focus on xenotransplantation, transgenic animals, cloning of animals and cloning of human cells and tissues from 1991 to the latest available survey from late 2005.[101] A new survey is currently in the making and is due to be conducted in early 2010. Survey research is but one of a whole range of instruments available to researchers studying the ways in which individuals, social groups and societies come to

[101] The series of EB Special surveys on Biotechnology and the Life Sciences are:
EB 35.1 (1991) Opinions of Europeans on Biotechnology in 1991 (EU12)
EB 39.1 (1993) Europeans and Biotechnology: What Europeans think about it in 1993 (EU 12)
EB 46.1 (1996) Europeans and Modern Biotechnology (EU 15)
EB 52.1 (1999) The Europeans and Modern Biotechnology (EU 15)
EB 58.0 (2002) Europeans and Biotechnology in 2002 (EU 15)
EB 64.3 (2005) Europeans and Biotechnology in 2005: Patterns and Trends (EU 25)
The reports of all the surveys with full technical specifications are available at
http://ec.europa.eu/public_opinion/archives/eb_special_en.htm

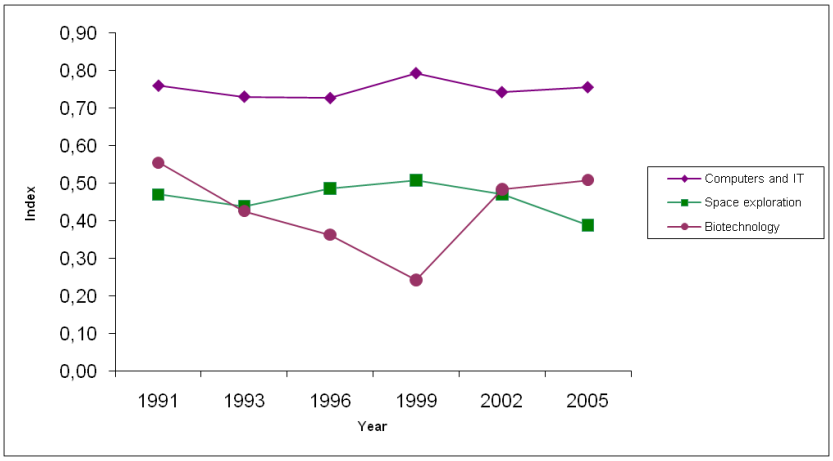
terms with the uncertainty and novel challenges brought about by scientific and technological developments. Critics argue that survey research might not always capture the whole range of hopes and concerns surrounding scientific and technological development as in most cases response alternatives are pre-determined and elements of public concerns might at times slip through the net. However, and notwithstanding such methodological caveats, survey research does remain a highly efficient, and cost-effective, instrument for mapping the distributions of given sets of beliefs across social constituencies and the diverse cultural areas of Europe. It is also an instrument that is particularly useful in terms of monitoring trends and shifts in the public mood over time. Further, it gives a unique opportunity to provide low resolution snapshots of the cultural climate surrounding the life sciences across the different European cultures at different moments for comparative purposes that might then inspire more fine-grained research approaches designed to capture nuances and ambiguities surrounding particular issues in more local contexts.

Further analysis of these surveys and several related research projects resulted in numerous publications, some of which are listed in the bibliography at the end of the paper.

5.7.2 Expectations concerning the future of biotechnology

All the surveys begin by gauging respondents' general expectations towards biotechnology in relation to a range of other technologies. From a methodological point of view this means that the interpretation of the terms is left open to the respondents. This is an index based on a relatively simple measure *"Do you think that (a named technology) will improve our way of life in the next twenty years, will make it worse or will not have an effect".* This index subtracts the pessimists from the optimists.

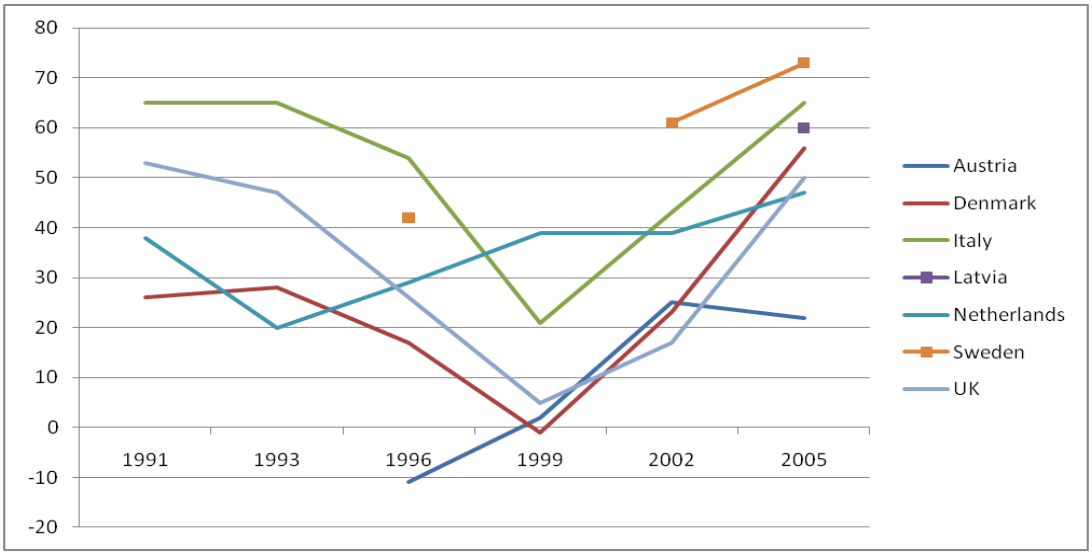
Figure 1: Levels of optimism towards biotechnology in Europe from 1991 to 2005[102]



[102] Source Gaskell, Allansdottir et al (2006)

This figure shows clearly that while optimism towards other technologies remained relatively stable between 1991 and 2005 there was a sharp drop in optimism towards biotechnology near the end of the millennium. As the new century unfolded, public optimism towards biotechnology began rising again. In short, there seems to be something rather particular about biotechnology in the public mind that aroused less optimism than other technologies, or put the other way around, gave greater cause for concern. Explanations as to why this might be the case could for example be sought in the furore over GM food and cloning in the winter of 1996 to 1997 or to shifting between a positively valued framing of biotechnology as a medical endeavour and a more negative framing in terms of food production. In any case the general story across Europe is worth telling but as with all general narratives it does conceal important differences between developing storylines in individual countries. In other words, it is therefore worth exploring further the trend in optimism towards biotechnology for the individual countries which are addressed in the CIT-PART project.[103]

Figure 2: Optimism towards biotechnology 1991-2005 in the countries participating in the CIT-PART project



The general trend shown in Figure 1 is represented by a sharp decline in optimism towards biotechnology, in contrast to the trend for the other technologies; from the mid nineties that is then followed by a marked return to earlier levels or even higher as the new millennium unfolds. Denmark, Italy and the UK were evidently a part of this general trend as can be seen in Figure 2, but the return to high levels of optimism is clearly much stronger in Denmark which moved from being amongst the more sceptical to being the relatively most optimistic in this timeframe.

[103] Latvia has been included in the Eurobarometer surveys after joining the European Community so time series data is not really available at the moment. Some similar surveys have been run in Canada and the US since 1996 but the data is not included here at this stage.

Because of a slight problem with the Swedish data in 1996 the line shown in 1999 unfortunately is not continuous, but in any case levels of optimism are consistently far higher than the European average.

The Netherlands seemed to be following a somewhat different path, optimism dropped sharply between 1991 and 1993 but steadily increased after that albeit not reaching the levels of optimism observed in the aforementioned countries. Austria is another country that seems to have followed its own path, upon entering the EU it ranked as quite pessimistic over the prospects of biotechnology but that then changed up until 2002 when levels of observed optimism towards biotechnology began declining again. Latvia, a newcomer to the EU, shows considerably high levels of optimism. Further research will give new insights into how national storylines unfolded and once the new Eurobarometer on Biotechnology and emerging technologies is in the public domain it will be possible to see how things have evolved in the meantime.[104]

The measures reported on above are very broad and general and should be interpreted as indicators of the general mood towards biotechnology in the relevant countries. The merits or usefulness of these measures in the context of the research conducted within the CIT-PART consortium are twofold. Firstly, the surveys provide longitudinal insights because they map the public mood over time and, secondly, they provide comparative insights because they allow us to compare the participating countries on the same scale. However, survey measures alone do not provide any indication as to the semantic connotations of biotechnology or genetic engineering over time and in different cultural contexts. The hope is very much that these somewhat crude representations of the swings in the public mood in the countries in question may give rise to some new research questions, insights or new issues to be taken up at later stages in this collaborative research.

The teams of research collaborations that were responsible for the design and analysis of the Eurobarometers on life sciences in European societies conducted research drawing upon a variety of quantitative and qualitative methods to analyse public and policy discourses, policy and media coverage of biotechnology. The results of the media studies are highly relevant in this context. The watershed years between 1996 and 1999 saw a veritable explosion of media attention to issues related to biotechnology. At the same time the separation of the public discourses surrounding green (agri-food) and red (biomedical) applications became more pronounced with growing public concern over the former and, seemingly, unfaltering support for the latter.[105]

[104] A new Eurobarometer survey on biotechnology and emerging technologies is in the final stages of preparation and will be conducted in early 2010.
[105] Bauer et al (2001)

5.7.3 European views on specific applications

The Eurobarometer surveys include a range of other measures of interest for the CIT-PART project. While the optimism measures pertain to biotechnology in general other sets of questions were designed to tap into whether respondents' perceptions differed according to applications. Beginning with the 1996 survey respondents were asked to give their views on a range of specific applications, reported below. For each application respondents were asked to indicate to what extent they agreed or disagreed that the biotechnology application in question was, ***useful*** for society, was ***risky*** for society, was ***morally*** acceptable and whether it should be ***encouraged***.[106]

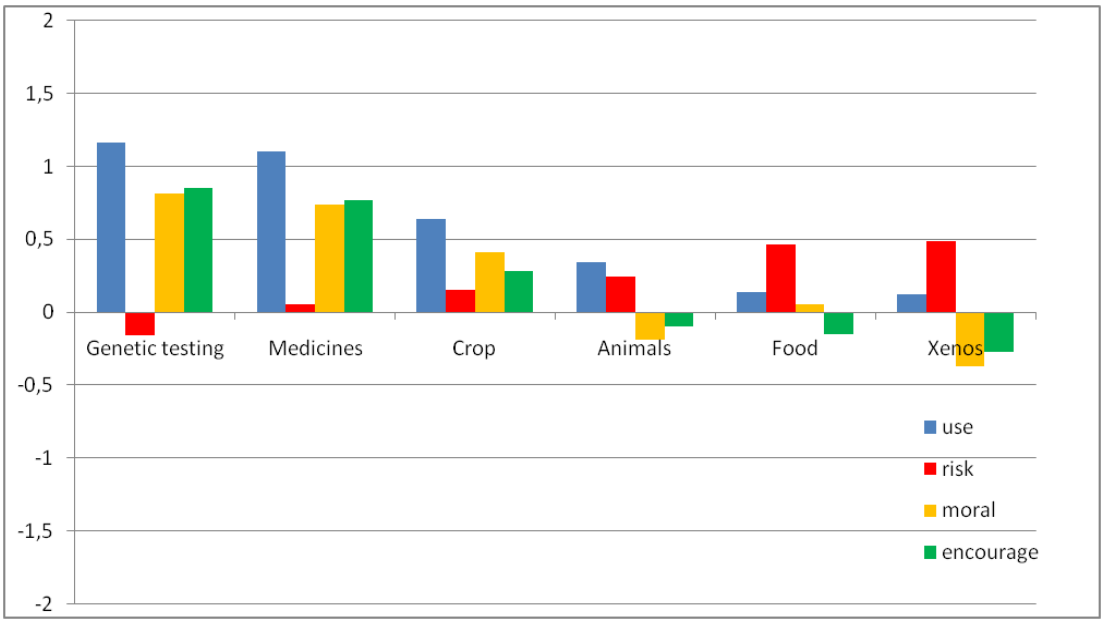
The following vignettes presenting six applications of biotechnology were presented to the respondents of the 1996 survey:

- **Genetic testing:** using genetic tests to detect inheritable diseases such as cystic fibrosis.
- **Medicines:** introducing human genes into bacteria to produce medicines or vaccines, for example to produce insulin for diabetics.
- **GM Crops:** taking genes from plant species and transferring them into crop plants to increase resistance to insect pests.
- **Transgenic animals:** develop genetically modified animals for laboratory research studies, such as a mouse that has genes which cause it to develop cancer.
- **GM Food:** using modern biotechnology in the production of foods, for example to make them higher in protein, keep longer or change the taste.
- **Xenotransplantation:** introducing human genes into animals to produce organs for human transplants, such as into pigs for human heart transplants.

For the present purposes the questions on transgenic animals and xentrotransplantation are of great interest; however it is worthwhile looking at public views toward those issues in the more general context of the range of applications included in the survey. Figure 3 presents the overall results of the survey for the 15 countries in the EU in 1996 but in general the trend was rather similar in all of the countries. Again, this might provide a nice opportunity for further analysis of particular contexts of interest.

[106] The respondents thus answered four questions for each application, all the questions had the same response alternatives (from definitely agree to definitely disagree) here converted into a scale from -2 to + 2.

Figure 3: Perceptions of selected applications of biotechnology in 1996[107]



In the light of the objectives of the CIT-PART project it is very interesting to report that out of the six applications included in the 1996 survey, xenotransplantation was clearly the least favoured amongst the Europeans. It was perceived as being risky, as of very limited utility, morally unacceptable and the general view was that it should not really be encouraged. The data was collected in November 1996 just before the furore over genetically modified food erupted in the public domain[108] but the results clearly showed that the European public was already concerned about GM food and was clearly hesitant to encourage the development of this application, which was seen as rather futile, at least compared to genetic testing and the development of new medicines; GM food was already seen as risky[109], morally questionable and as something which should not be encouraged. In many important ways these results were a sign of things to come, with seemingly strong support for biotechnology applied to medicine, with the notable exception of xenotransplantation and transgenic animals for research, but growing concern over agricultural and food applications.

The third application in the group that generated concern with the European public in 1996 was transgenic animals for research purposes, again an issue of great interest for the CIT-PART project. The application was seen as somewhat useful, but risky and morally unacceptable and it did not gather much support. There might possibly be two aspects of concern when it comes to transgenic animals for research purposes, one is the mixing of

[107] For further discussion about the general results from the 1996 Eurobarometer survey see: Gaskell et al (1997) and Gaskell et al (1998) for interpretations of the findings for individual countries taking part in this study see Allansdottir et al; Bauer et al, Fjæstad et al; Jelsoe et al; Midden et al; Wagner et al; (1998)
[108] Lassen et al (2002) Testing times.
[109] It might be of interest to note that the data was collected at the height of the BSE controversy.

species issue and the other is the appropriate use of animals for human exploitation, both are issues that persist in societal dialogues over biotechnology.

The next survey in the biotechnology and European society series was conducted in November 1999. This version explored, amongst other issues, the similarities and differences in public views on the cloning of human tissues and cells and the cloning of animals (reproductive animal cloning). Already at the end of the century the emerging field that later became known as regenerative medicine was of growing interest both for society and policy makers. This formulation was an attempt to explore the similarities and differences between perceptions of therapeutic cloning and reproductive cloning, an important distinction that entered the discourses on science policy in the life sciences towards the end of the millennium. The context is the story of Dolly that broke in early 1997[110] and the announcements of the extraction of stem cells from human embryos in 1998.[111] The public discourse developed in such a way that xenotransplantation came to be regarded by some as an alternative to therapeutic cloning of cells, in particular when based on cells derived from human embryos, as a solution to the growing societal problem of the lack of suitable organs for human transplants.

- **Genetic testing:** using genetic tests to detect inheritable diseases such as cystic fibrosis
- **Medicines:** introducing human genes into bacteria to produce medicines or vaccines, for example insulin for diabetics.
- **Bioremediation:** genetically modified bacteria to clean up slicks of oil or dangerous chemicals.
- **Cloning human cells:** cloning human cells or tissues to replace patient's diseased cells that are not functioning properly.
- **GM crops:** taking genes from plant species and transferring them into crop plants to increase resistance to insect pests.
- **Cloning animals:** cloning animals such as sheep to get milk which can be used to make medicines and vaccines.
- **GM food:** using modern biotechnology in the production of foods, for example to make them higher in protein, keep longer or change the taste.

[110] See Einsiedel et al (2002) for the story of Dolly in the limelight.
[111] Thompson et al (1998)

Figure 4: Perceptions of selected applications of biotechnology in 1999[112]

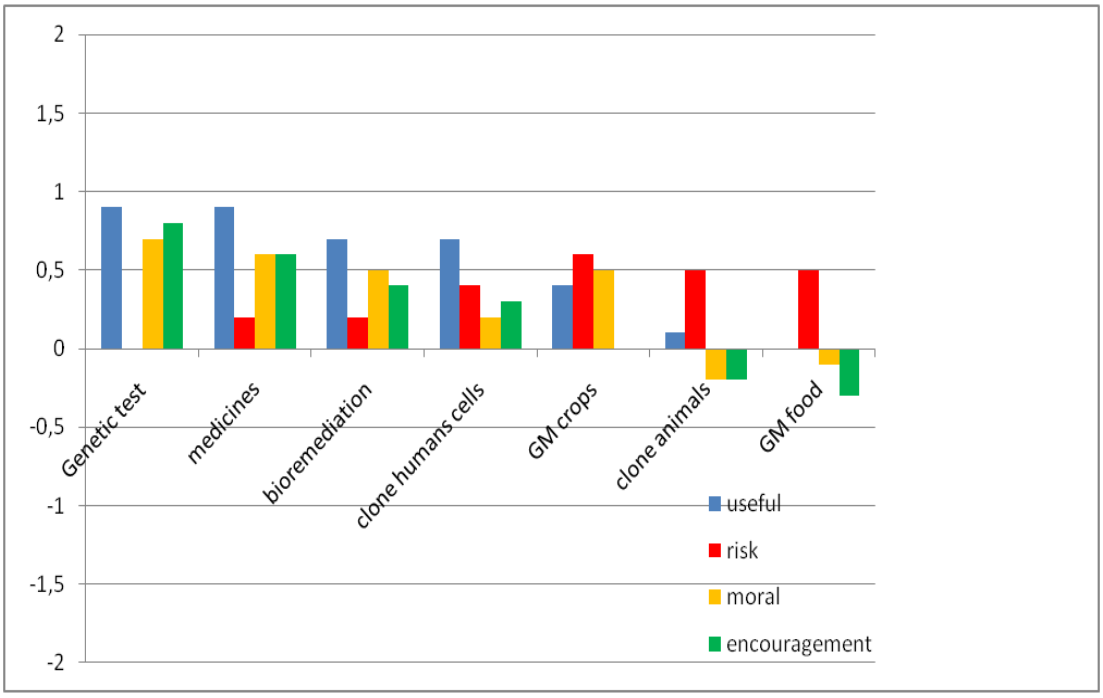


Figure 4 shows levels of support for six applications using the same four dimensions as before. Biomedical applications still enjoyed the highest level of support while agrifood applications were met with greater scepticism. This survey also included questions on bioremediation using explicitly the term *"genetically modified"* but as this application was perceived as useful, not all that risky and morally sound the term did not seem to taint public support. For our purposes, the differences in perceptions of cloning of human cells and the cloning of animals were frankly striking. The former was seen as useful, even if risky, morally acceptable and enjoyed some support. Cloning of animals, on the other hand, was seen as much less useful, very risky, morally unsound and was not to be encouraged.

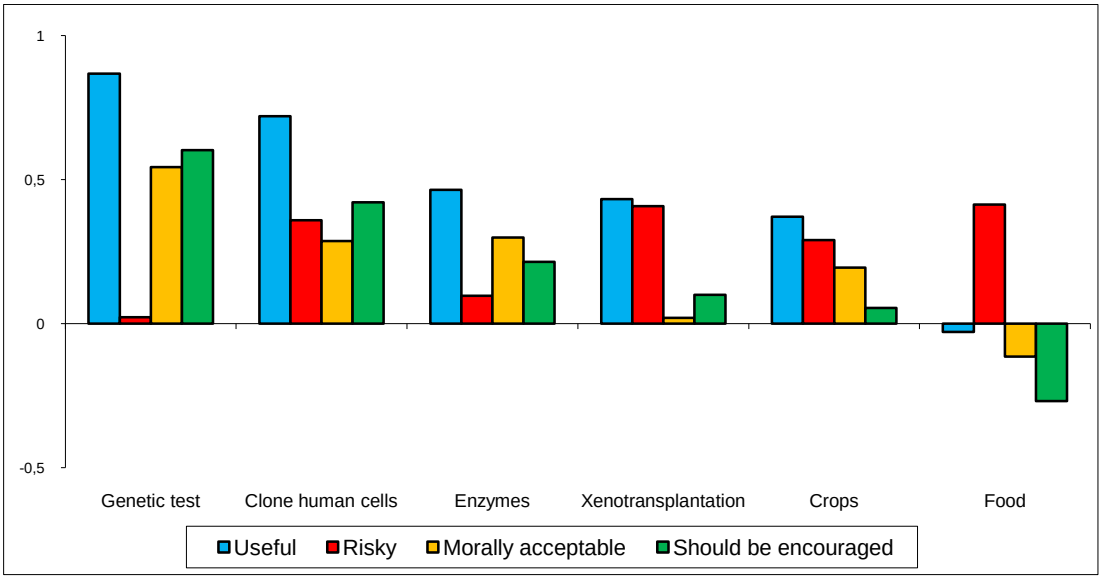
The next survey in the series on biotechnology and European society was conducted in 2002 and the results are presented in Figure 5. The logic of the questions remained the same but this survey included questions about xenotransplantation comparable to those used in 1996.

- **Genetic testing:** using genetic tests to detect inheritable diseases such as cystic fibrosis mucoviscidosis, thalassaemia.
- **Xenotransplantation:** introducing human genes into animals to produce organs for human transplants, such as into pigs for human heart transplants.

[112] For further discussions of the general 1999 data see Gaskell et al (2000), Gaskell et al (2001), and for the individual countries participating in the present study see the chapters by Allansdottir et al; Fjæstad et al; Gaskell et al; Gutteling et al; Jelsoe et al. & Torgersen et al (2001)

- **GM Food:** using modern biotechnology in the production of foods, for example to make them higher in protein, keep longer or change the taste.
- **GM Crops:** taking genes from plant species and transferring them into crop plants to increase resistance to insect pests.
- **GM Enzymes:** using genetically modified organisms to produce enzymes as additives to soaps and detergents that are less damaging to the environment.
- **Cloning human cells:** cloning human cells or tissues to replace a patient's diseased cells that are not functioning properly, for example, in Parkinson's disease or forms of diabetes or heart disease[113].

Figure 5: Perceptions of selected applications of biotechnology in 2002[114]



The most pertinent comparison here is between the perceptions of cloning of human cells and xenotransplantation. The cloning of human cells was seen as very useful, even if somewhat risky, morally acceptable and enjoyed strong levels of support. In comparison xenotransplantation was perceived as less useful than cloning, riskier, less morally acceptable and levels of support were considerably lower. It is to be noted that xenotransplantation was perceived as being as risky as GM food in 2002. The biggest change from 1996 was that xenotransplantation was more positively evaluated than GM crops, which had become viewed more negatively in the meantime. On the whole, xenotransplantation enjoyed a moderate level of support in all countries apart from Finland, Greece and Austria.

[113] Note that in the 1999 survey this question did not include the three examples of the uses of cloning human cells.
[114] For further discussion on the finding from the 2002 survey see Gaskell, Allum & Stares with Allansdottir et al (2003)

From the 1999 survey onwards these questions have been preceded by the question “have you heard of (the application in question)” and Table 1 shows self-reported levels of awareness of the six applications in 2002.

Table 1: Percentages of respondents stating that they have heard of a given application in 2002

Biotechnology application	
Genetic Testing	66,4%
Xenotransplantation	***65,4%***
GM food	63,7%
Cloning of human cells	62,3%
GM crops	58,6%
Enzymes	31,5%

The European public was clearly rather familiar with the issue of xenotransplantation in 2002 and slightly more reported having heard of xenotransplantation than therapeutic cloning/the cloning of human cells. That respondents report that they have heard of a given application of biotechnology is however not such a reliable indicator of levels of knowledge about that particular application and should primarily be used for comparative purposes. Table 2 shows levels of awareness of xenotransplantation in the countries participating in the CIT-PART projects in 2002.

Table 2: Percentage of respondents reporting to have heard of xenotransplantation in the CIT-PART participating countries in 2002

Country	
Sweden	86,4%
Denmark	83,1%
UK	81,5%
Netherlands	73,7%
Austria	69,5%
Italy	64,2%

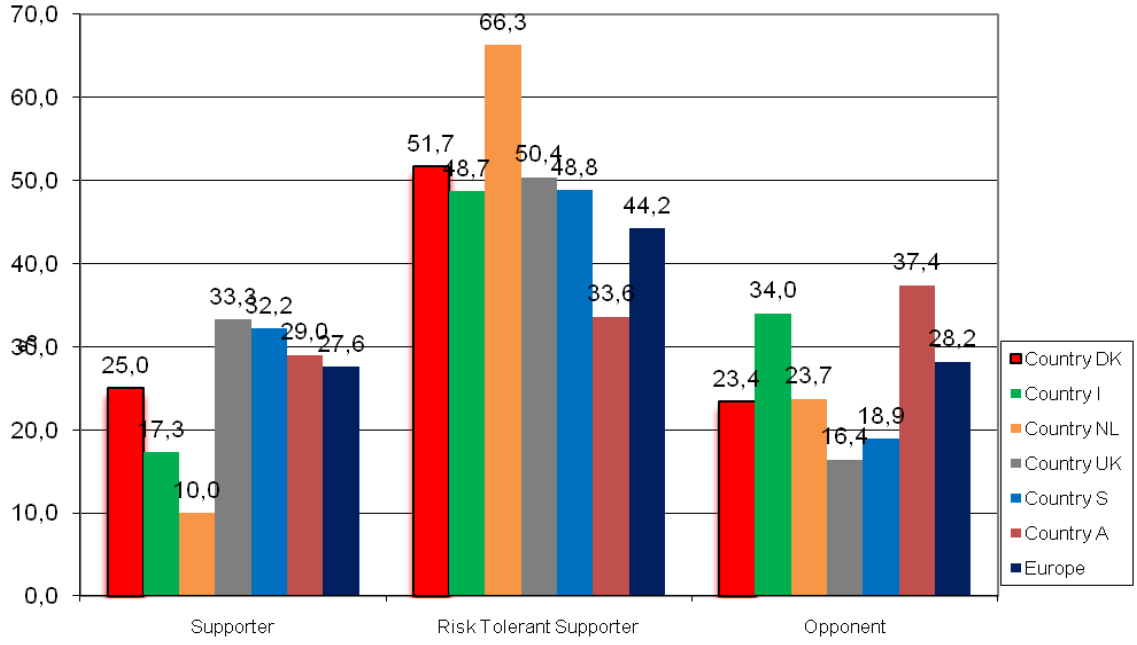
Levels of awareness were highest in the two Nordic countries participating in the study, a finding that is consistent with repeated findings that those publics as well as the Dutch tend to be more knowledgeable and better informed than the rest of the EU, closely followed by the UK.

5.7.4 Changes and logics of opposition and support for xenotransplantation

Some of the reports on the findings from the Eurobarometer series use a typology of the logics of support to simplify the exposition.[115] Using only data from those that express a clear opinion (excluding “don’t know” answers) the main logics are outright “supporters”, “risk tolerant supporters” - those who recognize the risks involved but are still supportive, and “opponents” - those who are simply against. Figure 6 shows the logic of views of the decided public in the CIT-PART countries (apart from Latvia and Canada) in 2002.

[115] Gaskell et al (1998, 2000, 2001 & 2003)

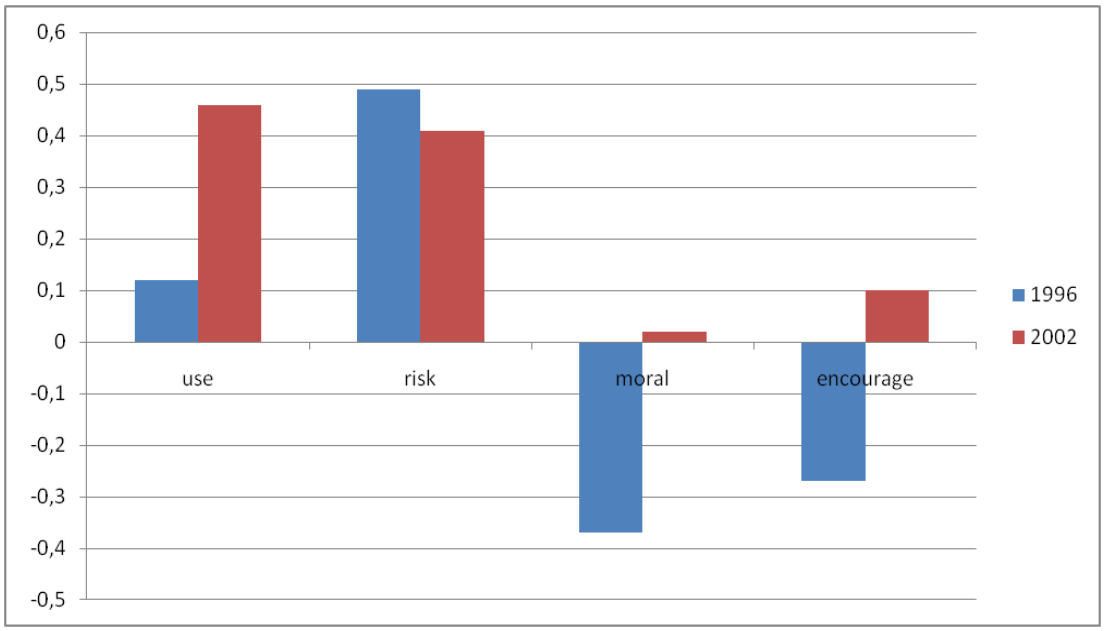
Figure 6: Logics of support and opposition to xenotransplantation in the CIT-PART countries in 2002



This presentation of the data includes only the decided public, that is to say those who answer “don’t know”, are excluded from the analysis and this particular graphical representation aims to be more informative than elegant. In most countries, the biggest category in this typology is that of the “risk tolerant” supporters, that is those that see the application as useful, recognise that there are risks involved but encourage the application all the same. This tendency is particularly strong in The Netherlands perhaps indicating a greater awareness of risk issues in general and possibly being more confident in the institutions managing those risks. The view of the Austrian public differs somewhat from those of the publics in the other countries. The biggest category is that of the outright opponents. In Italy the opponents outweighed the supporters but the highest category was that of risk tolerant supporters, while in the UK the supporters outnumbered the opponents.

Figure 7 shows the changes in public views on xenotransplantation from 1996 to 2002

Figure 7 Changes in public views on xenotransplantation from 1996 to 2002[116]



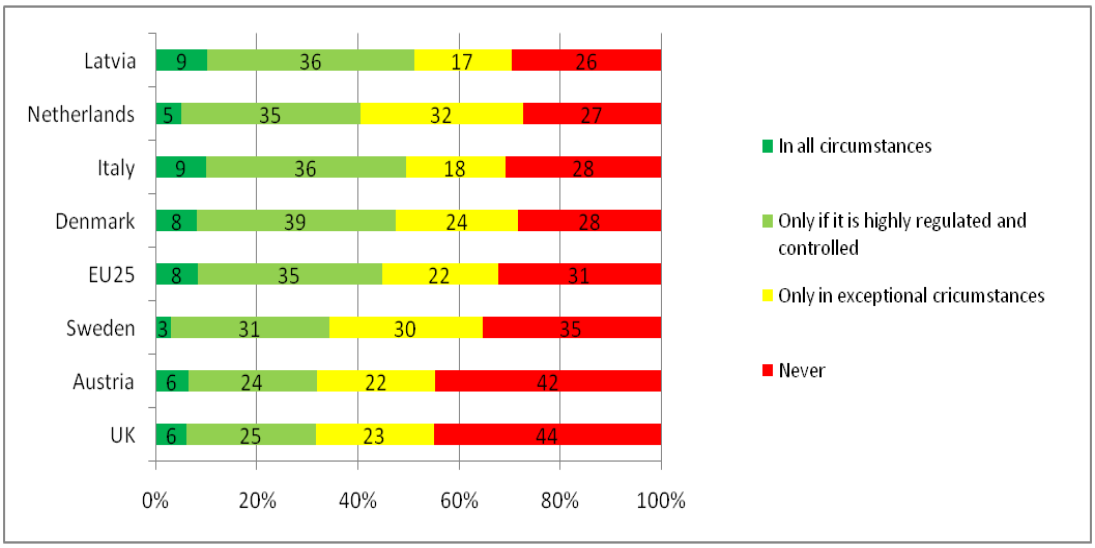
A methodological caveat is in order here because from 1999 these questions were preceded by the question "have you heard of x". However, it remains interesting to observe the changes between 1996 and 2002. The perceived utility had grown considerably by 2002 and the moral reservations had greatly weakened. This application was still seen as risky but overall the evaluation was considerably more positive than before. It is tempting to interpret these findings as the idea of xenotransplantation becoming more acceptable by losing some of the more "monstrous" connotations.

5.7.5 Cloning

Recent surveys have not included questions directly on xenotransplants but in the context of this chapter it might be interesting to look at perceptions of three different cloning issues; cloning of animals for research purposes; cloning of human tissues and cells (therapeutic cloning) and cloning humans to make babies (reproductive cloning). These findings were taken from a Special Eurobarometer survey "Social Values, Science and Technology" conducted in early 2005.[117]

[116] A new Eurobarometer survey is in preparation and wil be fielded in early 2010 with a battery of questions dedicated to regenerative medicine, including xenotransplantations.
[117] EB 63.1 Social Values Science and Technology.

Figure 8: Cloning animals such as monkeys or pigs for research into human diseases[118]

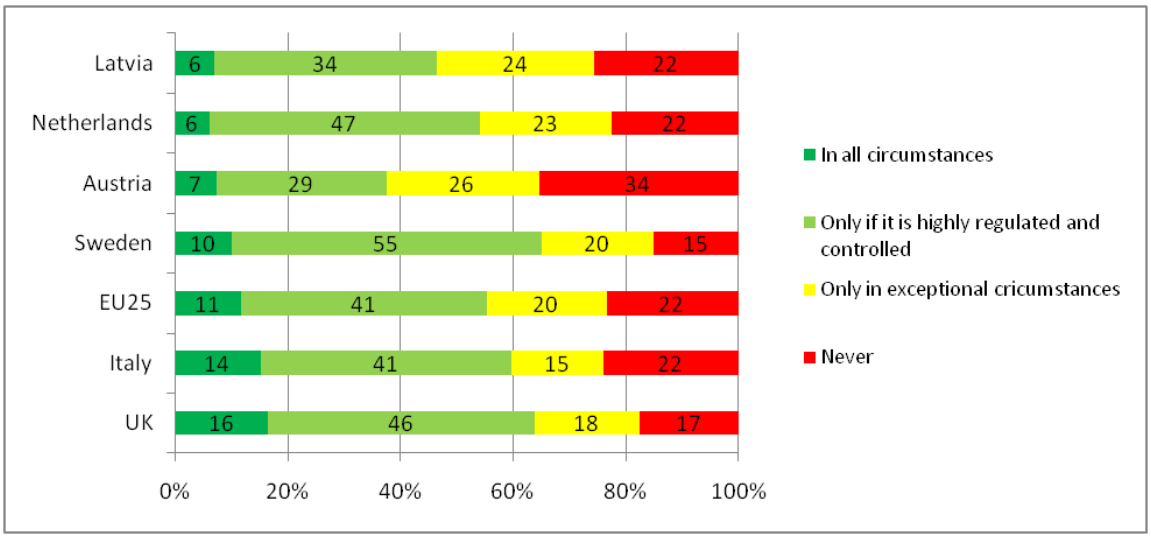


Opinions on animal cloning for research purposes in Europe are clearly strongly divided. As xenotransplantation involves harvesting tissues or organs from cloned animals these findings are highly pertinent for the CIT-PART project. Taking together those who would allow it in all circumstances and those who would like to see strict regulations and control, 43% of EU respondents are in favour (rising to 45% in Latvia and Italy) and 53% against (rising to 67% in the UK, 65% in Sweden and 54% in Austria). In any case this might indicate diverse views on appropriate use of animals and other issues relating to animal welfare dividing the European public, this is surely one of the issues to explore further in the case studies.

Moving from the animal kingdom to humans, the respondents were asked about their views on so-called therapeutic cloning and the results are reported in Figure 9.

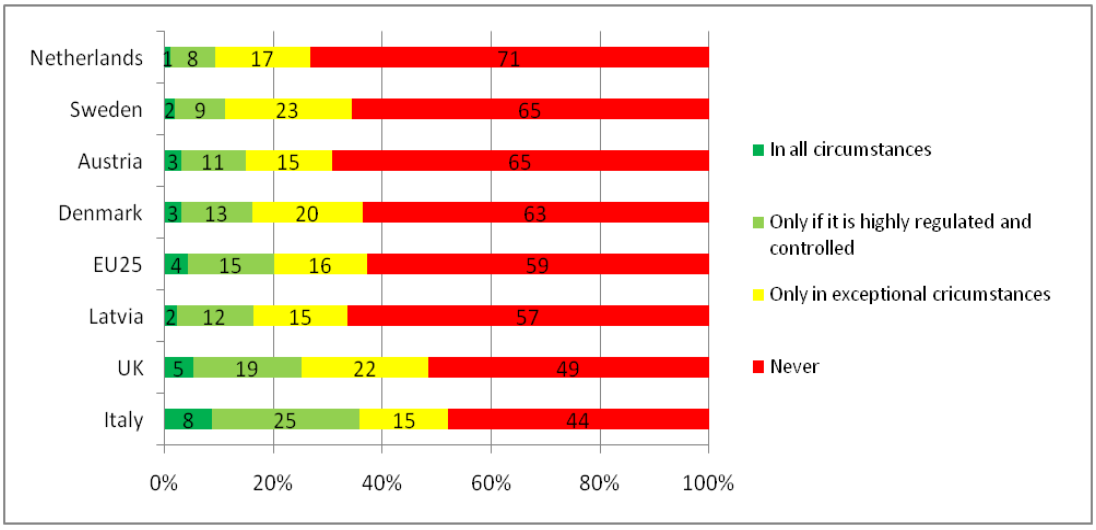
[118] Although the topic is very similar to the questions on therapeutic cloning used in the 1999 and 2002 surveys the response alternative have changed as the emphasis has moved to capturing people's views about regulatory issue as a direct input into policy making.

Figure 9: Cloning human cells from embryos to make cells and organs that can be transplanted into people with diseases



The opposition towards cloning of human cells from embryos is by far the highest in Austria while levels of acceptance above the EU average were observed in Italy, Sweden and the UK. This is consistent with other studies that have looked at the question of stem cell research in greater detail.[119]

Figure 10: Cloning human beings so couples can have a baby even if one partner has a genetic disease

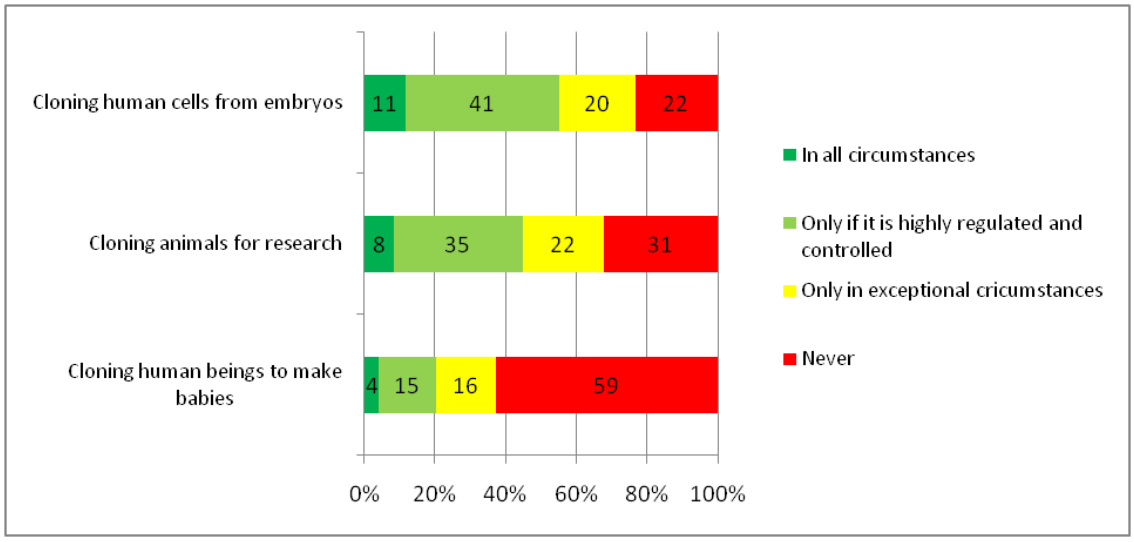


In general, the European public is clearly against the idea of cloning humans for reproductive purposes. But, somewhat against commonly held stereotypes, the Italians are those who are most open to the possibility of using cloning to make babies when one partner has a genetic

[119] See Gaskell, Allansdottir et al. (2006), Allansdottir & Hampel (2007)

disease with more than one of our four agreeing with that,[120] followed by the UK. At least in the Italian case this might be partly explained by the high value and expectations of having healthy children at all costs. Further, both the UK and Italy have had high levels of media coverage of reproductive technologies. The differences with the Netherlands, with 88% strongly against reproductive cloning compared to 59% in Italy are very striking.

Figure 11: European views on three types of cloning



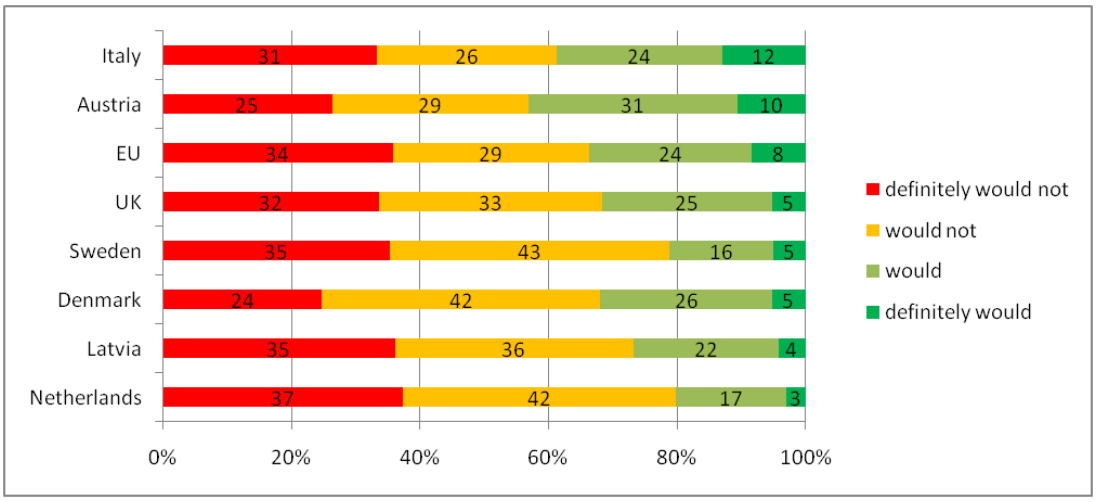
Generally speaking, there appears to be more widespread opposition to the cloning of animals, even with the noble aims of scientific research, than there is towards embryonic stem cell research. That said, the European public seems to draw the line at cloning humans to make babies. These findings are consistent with the results of the 2005 Eurobarometer on the Life Sciences which included a battery of questions on the issues surrounding stem cell research.[121]

[120] It is worth pointing out that the data was collected 4 months prior to the National referendum on reproductive technologies and embryonic stem cell in research that was held in June 2005.
[121] Gaskell et al (2006), Allansdottir & Hampel (2007)

5.7.6 Views on public participation

Surveys have attempted to tap into different national styles of engagement and participation in decision making on science and technology, using rather complex and composite measures that will not be included for the time being as this chapter is concerned with views, expectations and attitudes and not with self-reported actual or potential behaviour. However, one simple measure is included for the time being and the results are presented in Figure 12.

Figure 12: I would take part in public discussions or hearings about biotechnology.[122]



Both Italians and Austrian declare themselves more likely to take part in public discussions or hearings about biotechnology than the European average and the Swedes and the Dutch least likely to do so of the countries represented in this figure. This type of measure might actually say more about the culture of general participation in public events than anything about participation in science and technology.

5.7.7 Conclusions

This chapter was an attempt to give a short overview of the shifts and trends in public views on biotechnology from 1991 through to 2005 drawing upon existing material collected for the Eurobarometer Special surveys. The results show clearly that public expectations of biotechnology have gone through diverse stages, from relative optimism that simply caved in as the last century drew to a close only to rise again in the new millennium.

Public views clearly differentiate between various applications of biotechnology. The problematic story of GM in Europe is well known but that is a narrative rather distinct from those surrounding biomedical applications. As a general rule, medical biotechnology is

[122] For further details see Gaskell et al (2006)

favourably viewed by the European public but when it comes to xenotransplantation, the use of transgenic animals for research and the cloning of animals the stories become a lot more complicated and interesting cultural differences come to the fore.

Xenotransplantation is at times compared and contrasted with stem cell research as an alternative way to increase the offer of human cells, tissues or even organs for transplantation, given the problem of the shortage of suitable donors and long waiting lists. It does appear that the European public favours the stem cell solution over the xenotransplantation one, but future research may cast a better light on those issues.

5.7.8 References

Allansdottir, A & Bagnara, S (2001) Preface to Bioethics, Biotechnology and the Public: le notizie di Politeia, XVII, 63, pp. 6-12

Allansdottir, A. & Hampel, J. (2007) Religiosity, knowledge and levels of approval for stem cell research in Europe Presented to the session “Understanding European and North American public opinion towards biotechnology and nanotechnology”. San Francisco, CA. USA (2007); Annual Meeting of the American Association for the Advancement of Science (AAAS) Science and Technology for a Sustainable Wellbeing

Allansdottir, A., Pammolli, F. & Bagnara, S (1998) Italy. In J.Durant, M.W. Bauer & G.Gaskell (eds.) Biotechnology in the Public Sphere: A European Sourcebook. London: Science Museum. Pp 89-102.

Allansdottir, A., Bagnara, S., Angotti, L. & Montali, L (2001) Italy: from moral hazards to a cautious take on risks. In Gaskell, G & Bauer, M (eds) Biotechnology 1996-200: The years of controversy, London Science Museum. Pp 215-228

Bauer, M., Durant, J., Gaskell, G., Liakopoulous, M. & Bridgman, A (1998) United Kingdom in Durant, J., Bauer, M. & Gaskell, G. (eds) Biotechnology in the Public Sphere: A European Sourcebook. London: Science Museum. 162-176.

Bauer, M. & Gaskell, G. (2002) The biotechnology movement. In M. Bauer, G.Gaskell, & J.Durant (Eds.). Biotechnology- The making of a global controversy. Cambridge: Cambridge University Press, pp: 379-403.

Bauer, M. Kohring, M., Allansdottir, A & Gutteling, J. (2001) The dramatisation of biotechnology in elite mass media. In G.Gaskell, M. Bauer & J.Durant (eds) The years of controversy: Biotechnology 1996-2000. London: Science Museum, pp: 35-52

Durant, J., Bauer, M. & Gaskell, G. (eds) (1998) Biotechnology in the Public Sphere: A European Sourcebook. London: Science Museum

Einsiedel, E., A. Allansdottir, N. Allum, M. Bauer, A. Berthomier, A. Chatjouli, S. DeCheveigne, R. Downey, J. Gutteling, M. Kohring, M. Leonarz, F. Manzoli, A. Olofsson, A. Przestalski, T. Rusanen, F. Seifert, A. Stathopoulou, W. Wagner (2002) Brave new sheep – The clone named Dolly In: M. Bauer, G.Gaskell, & J.Durant (Eds.). Biotechnology- The making of a global controversy. Cambridge: Cambridge University Press, pp: 313-350

Fjæstad, B., Öhman, S., Olofsson, A., von Bergmann-Winberg, M-L., & Seger, N (2001)Sweden: the lid is on, but for how long? In Gaskell, G & Bauer, M (eds) Biotechnology 1996-200: The years of controversy, London Science Museum. Pp 267-281

Fjæstad, B., Olsson, S., Olofsson, A. & von Bergmann-Winberg, M-L. (1998) In Durant, J., Bauer, M. & Gaskell, G. (eds) Biotechnology in the Public Sphere: A European Sourcebook. London: Science Museum p. 130-143.

Galloux, J-C., Gaumont, H. & Stevers, E. (1998) Europe. In Durant, J., Bauer, M. & Gaskell, G. (eds) Biotechnology in the Public Sphere: A European Sourcebook. London: Science Museum. 177-185.

Galloux, J-C., Mortensen, A.T de Cheveignè, S. Allansdottir, A. Chatjouli, E & Sakellaris, G (2002) Bioethics: public concerns and political issues - a comparison of four EU countries. In In: M. Bauer, G.Gaskell, & J.Durant (Eds.). Biotechnology - The making of a global controversy. Cambridge: Cambridge University Press, pp: 129-148

Gaskell, G., Stares, S Allansdottir, A.,Allum, N., Hampel, J., Jackson, J., Kronberger, N.,Revuelta, G., Schreiner, C., Torgersen, H. and Wagner, Wolfgang (2006) Europeans and Biotechnologys in 2005. Patterns and Trends. Eurobarometer 64.3. Report to the European Commission. Directorate General DG XII Research http://ec.europa.eu/research/biosociety/pdf/eb_64_3_final_report_second_edition_july_06.pdf

Gaskell, G, Allum, N.C, Stares, S with Allansdottir et al: (2003) Europeans and Biotechnology in 2002: Eurobarometer 58.0, Brussels: European Commission. Aprile 2003.

Available: http://eurpo.eu.int/comm/public_opinion/archives/eb/ebs_177_en.pdf

Gaskell, G., Allum, N., Wagner, W., Hviid Nielsen, T., Jelsoe, E., Kohring, M & Bauer, M. (2001) In the public eye: representations of biotechnology in Europe.

Gaskell, G., Bauer, M. & Durant, J. (1998) Public perceptions of biotechnology in 1996: Eurobarometer 46.1 in Durant, J., Bauer, M. & Gaskell, G. (eds) Biotechnology in the Public Sphere: A European Sourcebook. London: Science Museum. P. 189-214.

Gaskell, G., Bauer, M., Allum, N., Lindsey, N., Durant, J., & Lueginger, J. (2001) United Kingdom: spilling the beans on genes. In Gaskell, G & Bauer, M (eds) Biotechnology 1996-200: The years of controversy, London Science Museum. Pp 292-306

Gaskell, G. & Bauer, M (eds) (2001) Biotechnology 1996-200: The years of controversy, London Science Museum

Gaskell, G and Biotechnology and the European Public Concerted Action Group (1997) Europe Ambivalent on Biotechnology. Nature, 26th of June.

Gaskell, G., N. Allum, M. Bauer, J. Durant, A. Allansdottir, H. Bonfadelli, D. Boy, S. de Cheveigné, B. Fjaestad, J.M. Gutteling, J. Hampel, E. Jelsøe, J. Correia Jesuino, M. Kohring, N. Kronberger, C. Midden, T.H. Nielsen, A. Przestalski, T. Rusanen, G. Sakellaris, H. Torgersen, T. Twardowski & W. Wagner (2000) . Biotechnology and the European Public. Nature Biotechnology, September 2000, 18, (9), 935 – 938

Gutteling, J., Midden, C., Smink, C. & Meijinders, A (2001) The Netherlands: controversy or consensus. In Gaskell, G & Bauer, M (eds) Biotechnology 1996-200: The years of controversy, London Science Museum. Pp 229-236

Hampel, J Allansdottir, et al (2006) Public mobilisation and policy consequences. In G.Gaskell & M Bauer (eds) Genomics and society. Ethical, legal and social implications. London: Earthscan

Jelsoe, E., Lassen, J., Thing Mortensen, A., Frederiksen, H., & Wambui Kamara, M (1998) Denmark Durant, J., Bauer, M. & Gaskell, G. (eds) (1998) Biotechnology in the Public Sphere: A European Sourcebook. London: Science Museum 29-42

Jelsoe, E., Lassen, J., Thing Mortensen, A. & Wambui Kamara, M. (2001) Denmark: the revival of national controversy over biotechnology. In Gaskell, G & Bauer, M (eds) Biotechnology 1996-200: The years of controversy, London Science Museum. Pp 157-171.

Kronberger, N., Dahinden, U., Allansdottir, A., Seger, N., Pfenning, U., Gaskell, G., Allum, N. C., Rusanen, T., Montali, L., Wagner, W., de Cheveigné, S., Diego, C., & Mortensen, A. (2001). “The train departed without us”: Public Perceptions of Biotechnology in ten European Countries. Le notizie di Politeia, XVII, 63

Lassen, J., Allansdottir, A., Liakopoulos, M., Mortensen, A.T & Olofsson, A (2002) Testing times – The reception of Round-up Ready Soya in Europe. In: M. Bauer, G.Gaskell, & J.Durant (Eds.). Biotechnology- The making of a global controversy. Cambridge: Cambridge University Press, pp: 279-312

Midden, C., Hamstra, A., Gutteling, J. & Smink, C (1998) The Netherlands. In Durant, J., Bauer, M. & Gaskell, G. (eds) (1998) Biotechnology in the Public Sphere: A European Sourcebook. London: Science Museum 103-111.

Torgersen, H., Egger, C., Grabner, P., Kronberger, N., Seifert, F., Weger, P., & Wagner, W (2001) Austria: narrowing the gap with Europe.

Wagner,W., N. Kronberger, G. Gaskell, N. Allum, A. Allansdottir, S. Cheveigné, U. Dahinden, C. Diego, L. Montali, A. Mortensen, S. Ohman, U. Pfenning, T. Rusanen (2001): Nature in Disorder: The troubled public of biotechnology. In G.Gaskell, M. Bauer & J. Durant (eds) In “The years of controversy: Biotechnology 1996-2000”. London: Science Museum pp: 80-95

Wagner, W., Torgersen, H., Seifert, F., Grabner, P. & Lehner, S. (1998) Austria. In Durant, J., Bauer, M. & Gaskell, G. (eds) Biotechnology in the Public Sphere: A European Sourcebook. London: Science Museum. P 15-28

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